UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA,	§	
	§	
VS.	§	CIVIL ACTION NO. H-10-759
	§	
CHUNG'S PRODUCTS LP, *et al*,	§	
	§	
Defendants.	§	

OPINION AND ORDER

Pending before the Court is the Government's Motion for Summary Judgment (Doc. 16), as well as Defendants Chung's Products, LP, Charlie A. Kujawa, and Gregory S. Birdsell's response (Doc. 30), the Government's reply (Doc. 34), Defendants' surreply (Doc. 38), the Government's response thereto (Doc. 41), Defendants' supplemental declaration (Doc. 47), and the Government's response thereto (Doc. 50). Upon review and consideration of this motion, the response, replies, and surreplies thereto, the relevant legal authority, and for the reasons explained below, the Court finds that the motion should be granted.

I. Background and Relevant Facts

This is a statutory injunction proceeding brought under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 331 *et seq*.

Defendant Chung's Products, LP ("Chung's") operates a food processing facility at 3907 Dennis Street in Houston, Texas. (Doc. 1 at 2.)

Defendant Charlie A. Kujawa ("Kujawa") is president of operations at Chung's. (Doc. 16, Exh. 2.) Kujawa represented Chung's at a regulatory meeting with Federal Drug Administration ("FDA") officials on March 6, 2008. (Doc. 16, Exh. 2C.) During the most recent inspection by the FDA in June 2009, Kujawa identified himself as the "most responsible

person"[1] at Chung's facility. (Doc. 16, Exh. 1.)

Defendant Gregory S. Birdsell ("Birdsell") was the director of quality assurance at Chung's. (Doc. 30, Exh. 2.) Birdsell also represented Chung's at a regulatory meeting with the FDA on March 6, 2008. (Doc. 16, Exh. 2C.) Along with Kujawa, Birdsell was the point-of-contact for FDA investigators during the two most recent inspections. (Doc. 16, Exh. 1.) Birdsell has since left Chung's, and Eddy T. Lee is now the director of quality assurance. (Doc. 50 at 1.)

Chung's facility falls under the dual jurisdiction of the U.S. Department of Agriculture ("USDA") and the FDA. (Doc. 30 at ¶ DJ1.) Chung's manufactures vegetable and shrimp egg rolls, which are regulated by the FDA, as well as chicken and pork egg rolls, which are regulated by the USDA. (Doc. 16, Exh. 1.) Chung's also imports prepared shrimp spring rolls from China, which it sells under the Chung's brand name. (*Id.*)

The FDA inspected Chung's facility in 2005, 2006, 2007, and 2009, documenting sanitation conditions and verifying food safety records. (Doc. 16, Exhs. 1H, 1G, 1D, 1B.) After each inspection, the FDA investigator issued observations on an FDA Inspectional Observation Form 483 ("Form 483"). (*Id.*) Each Form 483 documented numerous observations of noncompliance regarding sanitation practices and monitoring of food safety hazards. (*Id.*) The investigator discussed each of these observations with Birdsell and Kujawa during meetings prior to the issuance of the forms. (*Id.*) In addition, the FDA held meetings with Chung's following the 2006 and 2007 inspections. (Doc. 16, Exh. 2E, 2C.)

On October 30, 2007, the FDA issued a warning letter to Chung's citing "significant violations" of the FDCA and food safety regulations under. (Doc. 16, Exh. 2A.) Chung's sent

[1] "An individual who has the duty and power to act is a responsible person." Evidence of responsibility may include "[s]tatements by individuals admitting their responsibility or attributing responsibility to others." Fed. Drug Admin., Investigator Operations Manual § 5.3.6.

written responses to each violation and observation made at the four inspections and requested two meetings with FDA officials. (Doc. 30, Exh. A4 at 2.) Chung's says all issues were promptly resolved. (Doc. 4 at 2.) The Government alleges that despite "multiple warnings by the FDA, Defendants have demonstrated either inability or unwillingness to develop and implement adequate sanitation measures and an appropriate [Hazard Analysis Critical Control Point] plan to control the risk of microorganisms in their food." (Doc. 1 at 9.) The Government concludes that "[b]ased on their repeated course of conduct, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k) unless restrained by order of this Court." (Doc. 1 at 9.)

A. Sanitation

During each inspection of Chung's facility, the FDA documented recurrent sanitation concerns, including the use of unsanitary hoses, condensation problems, and poor employee hygiene. (Doc. 16, Exhs. 1H, 1G, 1D, 1B.)

At the 2005 inspection, the FDA investigator observed employees using filthy hoses "sitting in 6 inches of water" on the floor to clean a vegetable grinder and fill a tank of shrimp by submerging the hose in the tank. (Doc. 16, Exh. 1H.) At the 2007 inspection, the investigator again observed an employee on multiple occasions picking a hose off the floor to "either wash down equipment or fill the hand dip buckets or white 55 gallon barrel with water" used for moistening egg roll wrappers. (Doc. 16, Exh. 1D.) In April 2010, the Defendants' expert witness, Dr. Leslie Bluhm ("Bluhm") observed similar acts during his inspection. (Doc. 30, Exh. C at 4.)

At the 2005 inspection, the investigator also observed condensation dripping from an air conditioning unit to the floor near egg roll filling ingredients. (Doc. 16, Exh. 1H.) Condensation was again observed dripping from multiple air conditioning units in 2007. (Doc. 16, Exh. 1D.)

One unit leaked "directly over the final product conveyor belt." (*Id.*) Two other air conditioners leaked above ingredients in the filling room and "[c]ondensate was observed dripping into the shrimp egg roll filling." (*Id.*) In 2009, the investigator observed an accumulation of ice and debris, including discarded egg rolls on the floor of a freezer where finished egg rolls were stored. "According to Mr. Birdsell[,] the air-conditioning system had a leak and the ice formed due to the leak." (Doc. 16, Exh. 1F at 35.) The investigator also observed an "oily brown substance" running down the length of the wall of the refrigerator near raw egg roll wrappers and a "black, mold-like substance" on a shelf where raw chicken and onions were stored. (*Id.*)

At the 2005 inspection, the investigator observed employees handling garbage and then processing vegetables without washing their hands. (Doc. 16, Exh. 1H.) Again, at the 2007 inspection, the investigator reported that employees were handling bins of egg roll filling after using a floor squeegee without washing their hands. (Doc. 16, Exh. 1D.) One employee rinsed his hands in the water used for dipping the egg roll wrappers. (*Id.*) After the 2007 inspection, Chung's responded to these problems by conducting "on-site training of line workers in proper sanitation and personal hygiene practices." (Doc. 30, Exh. A8 at 2.) At the 2009 inspection, the investigator observed Defendant Birdsell not covering his beard with a beard net in the mixing room, as required by 21 C.F.R. § 123.11(b)(6) as well as by Chung's sanitation policy. (Doc. 16, Exh. 1F at 34.) Birdsell was "responsible for providing [sanitation practices] training" at Chung's. (Doc. 30, Exh. A17 at 8.)

B. Recordkeeping

The Government alleges Birdsell and Kujawa failed to cooperate with FDA investigators in providing sanitation records. The parties disagree whether Chung's properly disclosed its sanitation records during the 2009 inspection. The investigator reported:

> Mr. Kujawa and Mr. Birdsell would not provide all of the firm's sanitation records during the inspection. After several requests and a great deal of discussion . . . Mr. Birdsell explained that if I could name the document or identify the specific documents that I wished to see he would gladly provide them. . . . Mr. Birdsell was not willing to provide all the necessary sanitation records since I did not identify them by their individual title or document name. I specifically asked for the firm's records that covered the eight items of sanitation that are required to be maintained by a firm that manufactures seafood products.

(Doc. 16, Exh. 1F at 38.) Kujawa testified:

> In my presence, Mr. Birdsell . . . asked [the investigator] exactly what information he needed so that we could point it out to him and show him precisely where each required sanitation element was contained in our documentation and programs but [the investigator] was not able to define what he wanted to see.

(Doc. 30, Exh. A at 23.) Chung's gave the investigator documents containing its Sanitation Standard Operating Procedures ("SSOPs") and sanitation checklists for certain dates. (Doc. 30, Exh. A17 at 10.) SSOPs are recommended practices, not records of observations. 21 C.F.R. § 123.11. The checklists contained lists of sanitation items. (*Id*.) Next to each item was an "A" for "Accept" and an "R" for "Reject." Twice a day, an employee was to examine each item and circle the appropriate letter. (*Id*.) The items on Chung's sanitation checklists do not correspond to the eight requirements for Sanitation Control Records:

Required Sanitation Control Records (21 C.F.R. § 123.11)	Chung's Sanitation Checklists (Doc. 30, Exh. A17)
(1) Water safety (2) Cleanliness (3) Prevention of cross-contamination (4) Handwashing, toilet facilities (5) Control of food contaminants (6) Control of toxic chemicals (7) Control of sick employees (8) Pest control	A. Preoperational Checklist (1) Equip. (2) Walls (3) Floors (4) Ceiling B. Operational Checklist (1) GMP [Good Manufacturing Practice] (2) Equip. (3) Overhead

At the meeting after the 2009 inspection, Birdsell asserted that the eight sanitation items

required by 21 C.F.R. § 123.11 for seafood processors were included within the Good Manufacturing Practice ("GMP") item. (Doc. 16, Exh. 1F at 55.) GMPs are sanitation requirements for food processors. 21 C.F.R. § 110. They overlap to some extent with the eight items required for seafood Sanitation Control Records.[2] 21 C.F.R. § 123.11. However, GMPs do not require recordkeeping. Birdsell clarified that the GMP item in Chung's checklist referred to Chung's GMP policy, a three-page document containing forty-one GMPs. (Doc. 30, Exh. A17, Sub-Exh. 9.) The FDA investigator reported:

> I explained to Mr. Birdsell that I thought it would be very difficult for anyone to remember all the items on the three page GMP document and properly recognize the deficiencies and note them on the record without some type of further prompt. Mr. Birdsell assured me that his employees were capable of remembering the information and correctly filling out the GMP section of the records that were provided during the inspection.

(Doc. 16, Exh. 1F at 55.)

In its written response to the 2009 investigation, Chung's explained that the checklists actually referred to Chung's SSOP policy, not the GMP document identified by Birdsell. (Doc. 30, Exh. A17, Sub-Exh. 10-1.) Chung's refers to its SSOP policy document variously as "SSOP," "GMP SSOP," or "SSOP/GMPs," among other names. (*Id.*, Exh. A17 at 10.) Elsewhere in its written response, Chung's refers to its GMP policy document as "Chung's GMPs," its actual title. (*Id.*, Sub-Exh. 9; *Id.* at 8.) Kujawa refers to the same written response as the final authority on the matter:

> Chung's provided full documentation of its sanitation control records to [the] FDA in its [Form] 483 response and the completeness of our program in this area is further bolstered by the 2010 USDA [inspection] report and is confirmed by Dr. Leslie Bluhm in his Declaration.

(Doc. 30, Exh. A at 23.)

[2] "[S]ection 123.10 control procedures are identical in many respects to the previously prescribed GMPs in part 110 of the regulations." *The Statutory Basis for the FDA's Food Safety Assurance Programs: From GMP To 1995*, 50 Food & Drug Law Journal 357, 376.

The USDA's report states that Chung's SSOP records comply with 9 C.F.R. § 416.13(c), which governs meat and poultry processors. (Doc. 30, Exh. A12 at ¶ GS8.) However, the USDA report does not refer to 21 C.F.R. § 123.11, which contains the eight minimum Sanitation Control Records requirements for seafood processors. (*Id.*)

During the 2009 inspection, the FDA investigator asked Birdsell and Kujawa for documentation of egg rolls imported from China, as required by 21 C.F.R. § 123.12(a). The investigator reported, "During the inspection, I asked for a copy of the import documents for the last shipment of shrimp rolls from China. Both Mr. Birdsell and Mr. Kujawa denied my request for the information." (Doc. 16, Exh. 1F at 31.) Importers of seafood must make available to FDA investigators "written verification procedures" that ensure compliance with Hazard Analysis Critical Control Points (HACCP) regulations in the foreign facility, including (1) product specifications and (2) "affirmative steps" that "provide an equivalent level of assurance of compliance" as required for domestic facilities. 21 C.F.R. § 123.12(a).

There is disagreement between the 2009 Form 483 and Chung's response as to which documents were in fact provided to the investigator in regard to the imported egg rolls. The Form 483 states that Chung's "provided the case labeling and the final product labeling" for its imported egg rolls. (Doc. 16, Exh. 1F at 31.)

> Both Mr. Birdsell and Mr. Kujawa refused to provide this information during the inspection. Mr. Kujawa stated that it was not within the scope of my inspection even after I pointed out the specific import regulation during our discussion. I explained to Mr. Kujawa that the [Form 483] observation would remain on the [Form 483] since that is what occurred during the inspection and . . . information [provided] during the closing discussion was not sufficient to correct the deviation that was observed.

(*Id.* at 54.) Chung's response states that "Product Specifications for the Spring Rolls mentioned in the FDA [Form] 483 were given to the investigator during the close out meeting prior to the issuance of the FDA [Form] 483." (Doc. 30, Exh. A17 at 7.)

The 2009 Form 483 and Chung's response both mention an "HACCP Certificate" issued by the China Quality Certification Centre for "Processing of Arange [sic] of Roll Cabbage, Frozen Dumpling, Frozen Baozi, Frozen Chunjuan." (Doc. 30, Exh. A17, Sub-Exh. 8-1.) The certificate states, "Qingdao Longyuanfa Food Co., Ltd. . . . is in compliance and continually operating with CAC/RCP1-1969 Rev.4(2003) Guidelines for the Application of the [HACCP] System." (*Id.*)

Both the 2009 Form 483 and Chung's response also refer to "Sanitary" and "Quality" certificates issued by the "Entry-Exit Inspection and Quarantine" authority in China, which include basic shipping information. (*Id.*, Sub-Exhs. 8-3, 8-4.) Chung's provided an additional certificate asserting that "Qingdao Shiping [sic] Package Co., Ltd, guarantee the ingredients of following package that are don't contain leaded material, Will not hurt human health [sic]." (*Id.*, Sub-Exh. 8-8.) Kujawa visited the facility in China and concluded that the Chinese facility was "in compliance and even exceeding usual U.S. food manufacturing plant standards." (*Id.*, Sub-Exh. 8-6.)

Chung's states it "maintains at its location in Houston" documentation "for each shipment of imported Spring Rolls." (Doc. 30, Exh. A17 at 7.) However, at the 2009 inspection, Chung's did not provide the import documents for the most recent shipment. (Doc. 16, Exh. 1F at 30.) Chung's explained, "All of the records required by 21 C.F.R. § 123.9 are in fact retained at the processing facility in China. The investigator was advised of this fact during the

inspection." (*Id.*) Chung's does not explain how these documents and or its endorsement of the facility in China satisfy the requirements of 21 C.F.R. § 123.9–12.

During the 2009 inspection, the FDA investigator documented fourteen instances of refusals by Chung's to provide shipping documents as required by 21 U.S.C. § 374(a)(1), to allow taking of samples as required by 21 U.S.C. § 374(b), to disclose test results as required by 21 U.S.C. § 350c(a)(1), to permit observation of cooking facilities as required by 21 U.S.C. § 374(a)(1), to provide import documentation as required by 21 C.F.R § 123.9, and to permit photography. *See Dow Chemical v. United States*, 476 U.S. 227 (1986) (allowing photography by Environmental Protection Agency investigators and holding that "[w]hen Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission"); *United States of America v. Acri*, 409 F. Supp. 529 (S.D. Iowa 1976) ("[O]nce the validity of the inspection is established, the propriety of a photographic 'search' is coextensive with the validity of the inspection.")

The FDA investigator also complained that Birdsell "personally impeded" the 2009 inspection by delaying the entry of investigators for over four hours on June 18, 2009. (Doc. 16, Exh. 1F at 52.)

Chung's did not address these refusals in its response to the Form 483. (Doc. 30, Exh. A17.) Kujawa denies that he refused to permit observation of cooking facilities. Kujawa quotes Chung's minutes of the 2009 inspection: "After consultation with Mr. Kujawa, Mr. Birdsell granted the viewing. . . . [The inspection by Mr. Hurst continued in the Onion Room until complete, at 10.51 am.]" (Doc. 30, Exh. A at 24.) (brackets in original).)

The FDA investigator, by contrast, reported,

> On June 16, 2009, Mr. Greg Birdsell refused to allow me to observe the completion of the dehydrated onion cooking process. I was not allowed to observe the employee working in the dehydrated onion frying / cooking area moving the cooked product into the storage area within the normal working time frames of the facility. Mr. Birdsell stated that the onions would not be used in FDA products since the firm was producing USDA products. I was asked to leave the production area which I complied with immediately.

(Doc. 16, Exh. 1F at 51.) Chung's minutes state,

> [The investigator] asked who does the labeling [of fried onions] and where it goes after cooling. Employee responsible for frying onions does the labeling, and it stays in onion cooler until the end of production at which time it is transported to the cooler. 10:51 – Once completed, Mr. Birdsell told the inspectors that they have seen the process and since it is a USDA production day, they would need to leave the production facility.

(Doc. 30, Exh. D2.) Kujawa implies that the investigator "continued [the investigation] until complete, at 10.51 am," when, in fact, Birdsell expelled the investigators at 10:51. (Doc. 16, Exh. 1F at 51; Doc. 30, Exh. D2.)

C. Clostridium Botulinum

Chung's has a longstanding disagreement with the FDA over the inclusion of Clostridium botulinum ("C. botulinum") in Chung's HACCP plan. (Doc. 30, Exh. A4 at 2.)

Hazard Analysis Critical Control Points ("HAACP") is a "systematic approach to the identification, evaluation, and control of food safety hazards" mandated for seafood processors since 1997. Fed. Drug Admin., Hazard Analysis and Critical Control Point Principles and Application Guidelines (1997). HACCP regulations require processors to keep food safety and sanitation records and make them available to FDA investigators. 21 C.F.R. §§ 123.9(c), 123.11(c).

C. botulinum is a bacterium that produces "the most potent toxin known to man," causing the very rare but deadly disease botulism. (Doc. 16, Exh. 4 at 3; *Id.*, Exh. 3 at 5.) C. botulinum

proliferates in the viscera of shrimp and is more likely to appear in undeveined shrimp, which have intact digestive tracts or "veins." (Doc. 16, Exh. 3 at 5.) Chung's uses undeveined shrimp in its shrimp egg rolls. (*Id.*)

During each inspection from 2005 to 2009, the FDA investigator observed that Chung's did not list C. botulinum as a Critical Control Point ("CCP") in its HACCP plan. (Doc. 16, Exhs. 1H, 1G, 1D, 1B.) Listing a food safety hazard as a CCP obligates a processor to maintain safety records for that hazard. 21 C.F.R. § 123. Every hazard that is "reasonably likely to occur" based on the processor's mandatory hazard analysis must be listed as a CCP. *Id.* Chung's asserts that its decision not to list C. botulinum as a CCP was justified by its hazard analysis. (Doc. 30, Exh. A17 at 3.)

In 2009, the FDA investigator reported:

> During the close-out discussions with management, Mr. Birdsell and Mr. Kujawa both explained they did not agree with my inspectional findings . . . . They believed that the product does not have a hazard of Clostridium botulinum due to the history of the product and the in-house programs. Mr. Kujawa stated that his firm has a legal and correct HACCP plan for the production of his firm's shrimp egg roll product. He explained that he was certified in HACCP and that I was not and that I did not understand HACCP.

(*Id.* at 53.) The Government's expert witness, Michael Doyle ("Doyle"), director of the Center for Food Safety at the University of Georgia, questions the validity of Kujawa's HACCP qualifications. (Doc. 16, Exh. 4 at 17.)

Doyle also questions the validity of Chung's hazard analysis, which determined that C. botulinum is not a "reasonably likely" hazard in Chung's egg rolls sold in Modified Atmosphere Packaging ("MAP"). (Doc. 16, Exh. 4 at 17.) MAP is "the packaging of a product in an atmosphere which has had a one-time modification of gaseous composition, rendering it different from air." (Doc. 16, Exh. 3 at 9.) MAP is typically used for food sold in refrigerated deli or

supermarket display cases, rather than freezers. (*Id.*)

> [MAP] can extend the shelf life of fish and meat products at a reasonable cost by removing or reducing oxygen from the packaging. . . . Such packaging, however, presents a public health risk because it may not only extend shelf life, but also gives C. botulinum a chance to grow, with less or no competition from spoilage flora and no obvious signs of spoilage.

(Doc. 16, Exh. 4 at 5.)

Doyle states, "Chung's failure to list C. botulinum as a food safety hazard leads me to question whether the firm understands HACCP, as a HACCP-certified individual familiar with C. botulinum would list this as a hazard for a seafood-based product packaged in [Modified Atmosphere Packaging] that is to be sold at refrigeration temperature." (*Id.*) Doyle does not address whether the hazard is "reasonably likely" as defined by 21 C.F.R. § 123.6(a).

After the 2005 inspection, the FDA instructed Chung's that, if it chose not to follow the FDA's Fish and Fisheries Products Hazards and Controls Guidance, it "must show a rationale for why the product is safe against *Clostridium botulinum* for the shelf life claimed, under conditions of mild abuse." (Doc. 16, Exh. 2E at 3.) Chung's responded that it would arrange a challenge study through the National Food Processors Association ("NFPA") to test for C. botulinum in egg roll packages at different temperatures.

On February 21, 2006, Chung's hired National Food Laboratory, Inc. to conduct the study, and it sent the FDA a copy of the testing protocol. (Doc. 30, Exh. A18.) On April 3, 2006, Chung's wrote, "[T]he agency has never provided us with any comments concerning National Food Laboratory test protocol. Chung's viewed this fact to mean the study protocol is not one to which [the] FDA would or will fault after the final results are known." (*Id.*)

The challenge study detected C. botulinum in a sample stored for six days at 30°C, but not in a sample stored for twenty-eight days at 12°C. (Doc. 16, Exh. 3C.) Chung's egg rolls

were labeled for a twenty-eight day shelf life when kept in deli cases, which are typically maintained at approximately 10°C (50°F). (Doc. 16, Exh. 4 at 8.) However, all the samples "became overtly spoiled before toxin was produced." (Doc. 16, Exh. 3C.) Chung's asserted that the challenge study "confirms . . . that C. botulinum is not reasonably likely to occur . . . ." (Doc. 30, Exh. A4 at 5.)

The FDA raised several objections to the test results, including the possibility that C. botulinum growth had been inhibited by spoilage or competition between strains of inoculated C. botulinum, as well as the lack of a "positive control" for non-proteolytic strains of C. botulinum. (*Id*. at 2; Doc. 16, Exh. 3 at 16.) A positive control is a test sample in which bacterial growth occurs. Non-proteolytic C. botulinum is one of two major groups of C. botulinum:

> The proteolytic group produce[s] enzymes that degrade proteins, causing offensive odors and tastes in a food product. Consumers therefore could smell or taste spoilage in food products contaminated with proteolytic C. botulinum. By contrast, the non-proteolytic group of C. botulinum which can grow at refrigeration temperatures as low as 38 degrees Fahrenheit may render a food toxic without any apparent signs of spoilage. Non-proteolytic strains, therefore, are particularly dangerous to consumers.

(Doc. 16, Exh. 3 at 6.) A positive control for non-proteolytic C. botulinum in the challenge study would have demonstrated that

> selected strains of C. botulinum used to inoculate the egg rolls samples were capable of producing toxin in a component[3] of the food. Once [toxin production is] shown, a positive control would then allow the laboratory to determine what attribute, for example, the egg roll formulation, controlled the production of toxin in the finished egg roll. Without a positive control, the Challenge Study does not reveal whether the laboratory was able to detect toxin in the food, nor does it reveal whether the product as formulated prevented the C. botulinum strains from producing toxin.

[3] "Many challenge products have multiple components or layers. If contamination during assembly is possible, the challenge inoculum should be applied to the various layers or components. Unique growth conditions can exist at the interfaces between components, such as the microenvironment between a pie crust and a pie filling." National Advisory Committee on Microbiological Criteria for Foods, Parameters for Determining Inoculated Pack/Challenge Study Protocols 150, J. Food Prot., Vol. 73, No. 1 (2010).

(Doc. 3 at 17.)

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), recommends using only non-proteolytic strains of C. botulinum to perform challenge studies on refrigerated foods.[4] (Doc. 16, Exh. 3 at 17.) The challenge study performed by National Food Laboratory, however, employed a mixture of proteolytic and non-proteolytic strains of C. botulinum that "may have competed with each other to prohibit toxin growth." (*Id*. at 17; Doc. 16, Exh. 3C.) Doyle, the Government's expert, explains,

> This study is flawed for many reasons. First, the study does not make clear whether C. botulinum strains used by [National Food Laboratory] could grow and produce toxin, i.e. a positive control was lacking. Accordingly, it is unclear whether toxin was not produced in the egg rolls because the egg rolls are formulated in a way that prohibits the growth, or because the strain used would not have produced the toxin under any conditions. The purpose of a positive control for such studies is to ensure that the C. botulinum culture used to inoculate the food is viable and able to produce detectable concentrations of botulinum toxin. It confirms that the test is functioning properly.

(Doc. 16, Exh. 4 at 15.)

In response to the FDA's objections, National Food Laboratory stated that "[v]iability of . . . *C. botulinum* is checked by platting [sic] the inoculum. . . . There is not a 'product positive control' since the question we are trying to answer with the study is, will *C. botulinum* grow (remain viable), and produce toxin?" (Doc. 16, Exh. 3D at 3.) "Plating" is a method of preparing inoculum in food studies by placing a small amount of bacteria on an agar plate, from which healthy portions are extracted, analyzed, and then injected into a food sample, such as a positive control sample. Fed. Drug Admin., Bacteriological Analytical Manual ch. 17 (1998).

"Check[ing] the viability of C. botulinum by platting [sic] the inoculum" does not address

[4] NACMFC is a scientific advisory committee instituted in 1988 to advise the USDA and the FDA on food safety systems. *See also* Food Directorate, Health Canada, *Clostridium botulinum* Challenge Testing of Ready-to-Eat Foods ¶ 5.1 (2010) ("Cocktails containing multiple proteolytic strains and cocktails containing nonproteolytic strains should be tested separately to account for potential strain variation.")

the FDA's criticism whether "the selected strains of C. botulinum used to inoculate the egg rolls samples were capable of producing toxin *in a component of the food*," nor does it "reveal whether the product as formulated prevented the C. botulinum strains from producing toxin." (Doc. 16, Exh. 3 at 17 (emphasis added).) It is possible that culturing C. botulinum in an egg roll sample, as a positive control sample, would require adjusting factors such as acidity, water activity, or salt. Fed. Drug Admin., Bacteriological Analytical Manual ch. 17 (1998). This would add a layer of sophistication to the experimental design, beyond what might be typical of food challenge studies.[5] Nevertheless, the lack of a positive control remains a valid criticism. Rather than address the challenge study's limitations, Chung's insisted it was valid and that the results justified Chung's decision not to list C. botulinum in their HACCP plan. (Doc. 30, Exh. A4 at 5.)

Unexpectedly, the challenge study found indications of spoilage prior to the egg rolls' use-by date. (Doc. 16, Exhs. 4 at 15, 3D at 6.) At twenty days, lobster egg rolls stored at 12°C (50°F) showed signs of spoilage, including off odors and mold. (Doc. 16, Exh. 3C.) Shrimp egg rolls showed signs of spoilage at twenty-eight days. Doyle stated,

> As a matter of industry best practice, [Chung's] should have altered its shelf life based on this study; if the product had signs of spoilage within twenty days at temperatures that occur in the home or at retail, the shelf life of the products should be less than twenty days, not the twenty eight days that the firm currently uses.

(Doc. 16, Exh. 4 at 15.)

Chung's subsequently reduced the labeled shelf life of its lobster egg rolls to twenty-one days, one day longer than the twenty days indicated by the study. (Doc. 16, Exh. 1D.) Two

[5] "Positive controls could be included in the experimental design to ensure that toxin, produced in the food product, can be detected in analysis of the food product. Depending upon the food product, key safety parameters may need to be altered to enable production of toxin in the food product. For example, unacidified shrimp could serve as the positive control for acidified shrimp." Food Directorate of Canada, Clostridium botulinum Challenge Testing of Ready-to-Eat Foods (2010).

years later, Chung's discontinued its lobster egg rolls. (Doc. 16, Exh. 1F at 54.) Chung's continues to sell shrimp egg rolls with a labeled shelf life of twenty-eight days, a duration in which spoilage was observed. (Doc. 16, Exhs. 1D, 1F at 10.)

In 2009, Chung's changed the formulation of its egg rolls. (Doc. 30, Exh. A17 at 6.) Doyle testifies:

> Chung's has altered its formulation at least two times since the Challenge Study . . . by using cooked rather than raw frozen shrimp . . . [and] switch[ing] from raw onions to dehydrated onions. Either of these changes could have substantially altered the aerobic spoilage flora of the product which compete with C. botulinum. . . . Because of these changes, the Challenge Study, which was flawed when originally conducted, cannot be relied on by the firm currently.

(Doc. 16, Exh. 4 at 16.) Prior to the change in product formulation, Chung's had told the FDA

> [i]f Chung's were to change the formulation of the product this Challenge Study would not be applicable to that new formulation. . . . Should Chung's in the future determine to change ingredients in its egg roll products, it is logical to have [National Food Laboratory] or some similar qualified testing laboratory conduct another Challenge Study to verify that C. botulinum continues to not be an issue. This notation will be in the HACCP plan at Chung's to make sure no problems arise in the future.

(Doc. 16, Exh. 3D at 4.)

At the meeting in 2008, "[i]n response to a question from [the FDA] about changing onions over the course of time, Mr. Kujawa said that Chung's only used onions that are not sweet to maintain an even product." (Doc. 16, Exh. 2C at 3.) During the meeting, the FDA and Defendants discussed "how holding to a formulation is a key to consistent product without continually changing the formulation and then having to consider another Challenge Study. Mr. Kujawa and Mr. Birdsell mentioned that each ingredient in the egg rolls has precise specifications that are provided to all vendors." (Doc. 16, Exh. 2C at 3.)

During the 2009 inspection, the FDA investigator observed that Chung's had, in fact,

switched to dehydrated onions. (Doc. 16, Exh. 1B.) When the investigator inquired why Chung's had not informed the FDA of the change, Birdsell said "recipe information is confidential and proprietary." (Doc. 30, Exh. D2.) The Product Specification sheet for Chung's shrimp egg rolls, dated February 2008 and presented to the FDA in August 2009, indicates that "[f]resh vegetables are peeled and washed," but does not mention dehydrated onions. (Doc. 16, Exh. A17, Sub-Exh. 8-7.) Chung's also failed to list the change of ingredients on its HACCP Updates chart. (Doc. 16, Exh. 1F at 54.) On April 21, 2009, Chung's made seven entries to its HACCP Updates chart, including entries for discontinuing egg rolls containing lobster and outsourcing the mixing of spices but not including the change in onions. (Doc. 30, Exh. A17, Sub-Exh. 5.) Chung's stated:

> At the time Chung's determined to modify the make-up of MAP Shrimp egg rolls by switching from fresh onions to dried onions the HACCP was in fact followed. While formula change information is confidential and proprietary, the water activity [i.e., moisture content, a barrier for C. botulinum in food products] of Shrimp egg rolls was monitored before the change, during the change and following the formula change.

(Doc. 30, Exh. A17 at 6.) Chung's testing records indicate that water activity levels in its egg rolls were tested on February 26 and again on May 7, 2009. (*Id.*, Sub-Exh. 7.) However, there is no indication whether these tests occurred "before the change, during the change [or] following the formula change." (Doc. 30, Exh. A17 at 6.) The FDA investigator reported in June 2009, "There is no way to tell when the change in the process occurred. There is no documentation of the ingredient change in any of the firm's HACCP documents that were provided during the inspection." (Doc. 16, Exh. 1F at 29.)

During the 2008 meeting, an FDA official noted that "a change in suppliers might have a cascade effect requiring additional Challenge Studies." (Doc. 16, Exh. 2C at 3.) The Government's expert, Doyle, testifies:

> Changing the producer of shrimp, depending on its source, may also require a new Challenge Study because the source of the shrimp could use raw chicken manure and fish waste as nutrients in ponds and have a higher prevalence and concentration of C. botulinum type E spores than shrimp grown in open water.

(Doc. 16, Exh. 4 at 16.) Chung's states that it "do[es] not think a specific vendor plays any role." (Doc. 30, Exh. 3D at 4 n.1.)

Chung's claims to have extensively researched different egg roll formulations to control C. botulinum, including by using ingredients such as nisin and acid. (Doc. 30, Exh. A18 at 3.) At the same time, Chung's insists that its "egg roll ingredients are all typical food ingredients with a formulation that has not changed for years." (Doc. 16, Exh. 3D at 5 n.1.)

Chung's fails to demonstrate that it retested its egg rolls or reassessed its HACCP plan upon making changes to its formula, suppliers, or ingredients.

D. Water Activity as a Secondary Barrier for C. Botulinum

The FDA's Fish and Fisheries Products Hazards and Controls Guidance recommends that MAP-packaged fish and fishery products have a "secondary barrier" to prevent growth of C. botulinum, in addition to the primary barrier, temperature, which is maintained through refrigeration. (Doc. 16, Exh. 4 at 11.) The FDA's Guidance is not compulsory. "An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations." (*Id.* at 1; Doc. 16, Exh. 3 at 15.)

Recommended secondary barriers for C. botulinum include "controlling the level of pH to 5 or below, salt to 5% wps or more, moisture (water activity) to 0.97 or below, or some combination of these barriers." Fed. Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance 250 (4th ed. 2011). "MAP packaging itself is not such a barrier; rather it is a risk because it is what promotes C. botulinum toxin formation by creating a long-term reduced

oxygen or anaerobic environment." (Doc. 16, Exh. 4 at 11.)

Water activity is a measure of the moisture content of food, measured on a scale of zero to one, with pure water having a level of one. (Doc. 16, Exh. 3 at 14.) Foods with a level of 0.85 or less, such as dried fruits or nuts, do not support pathogenic bacteria and can be stored without refrigeration. (Doc. 16, Exh. 3 at 14.) The FDA has determined that a water activity level of 0.97 or below may serve as a secondary barrier for C. botulinum. (*Id.*; Doc. 30, Exh. C at 6.)

In response to the FDA's 2007 warning letter, Chung's requested a meeting with FDA officials at the FDA's Center for Food Safety and Applied Nutrition ("CFSAN") in Maryland. (Doc. 30, Exh. A8.) At the meeting, "Chung's stated that it would control for the risk of C. botulinum by monitoring the water activity of its shrimp egg rolls and ensuring that this level was maintained below 0.97." (Doc. 16, Exh. 2 at 5.) Chung's minutes state:

> [Chung's attorney] announced that very recently Chung's had conducted water activity testing of its [shrimp egg rolls] and that the results were water activity of less than 0.97. The significance of this result is Chung's has demonstrated it has a secondary barrier to these products as provided for in FDA Guidance, Fish and Fisheries. . . .
>
> Mr. Kujawa explained that only recently had he become aware of the fact that Chung's had not previously tested its egg rolls for water activity. He had experience with water activity while working in the food industry and decided to have the tests run. Mr. Kujawa stated Chung's would monitor water activity each day that shrimp and seafood egg rolls are produced for three months to verify the level is consistently below 0.97, and then monitor quarterly going forward. This was agreeable to the agency.

(Doc. 16, Exh. 2C at 3.)

Consumer safety officer Mary Losikoff ("Losikoff") of CFSAN testifies, "This promise was a step in the right direction[;] however, as demonstrated during the 2009 inspection, [Chung's] failed to live up to this promise and has yet to include water activity as a critical control point in its HACCP plan . . . ." (Doc. 16, Exh. 3 at 24-5.) Kujawa responds, "Contrary

to the statements by Ms. Losikoff . . . not one word was said by *any* FDA official present at the 2008 meeting that *additionally* Chung's should list [w]ater activity as a critical control point (CCP) in . . . Chung's HACCP plan." (Doc. 30, Exh. A at 11.)

During the 2009 inspection, the FDA investigator sent samples of Chung's shrimp egg rolls to the FDA's laboratory for water activity testing. Levels ranged from 0.975 to 0.982, averaging 0.979. (Doc. 16, Exh. 2D.) Chung's claims it sent identical samples to a private laboratory for testing. (Doc. 30, Exh. A11.) Two of Chung's samples had water activity levels of 0.976, although the average levels were lower. (*Id.*) Chung's attorney noted:

> The results of the two tests are not the same. . . . An examination of the samples side by side fails to disclose any consistent differences. For example, in sample no. 4 the FDA laboratory reported the highest water activity, 0.982 while [the private laboratory] reported the sample pulled at the same time and place to have a water level activity of 0.968, the third lowest reading by [the private laboratory].

(*Id.*) The investigator reported that "due to the discrepancy between [Chung's] own water activity results and the sample that I collected during the inspection, Mr. Birdsell and Mr. Kujawa stated [that] changes to the shrimp egg roll product are under research and development by the firm." (Doc. 16, Exh. 1F at 26.) Defendants do not dispute that Chung's egg rolls tested above 0.97 in both Chung's and the FDA's tests.

During the 2009 inspection, the FDA investigator reviewed results of voluntary water activity tests undertaken by Chung's since the 2008 meeting, noting three instances when levels exceeded 0.97. (*Id.* at 23.) The investigator also reported that Birdsell and Kujawa refused to allow photocopying of Chung's water activity testing records. (Doc. 16, Exh. 1F at 51.) Birdsell and Kujawa protested the taking of samples for testing and prevented the investigator from leaving the facility with the samples without first issuing a Form 484 receipt, which impeded taking routine random samples. (Doc. 16, Exh. 1F at 51.) A Form 484 receipt is typically issued

along with the Form 483 at the end of each inspection. Fed. Drug Admin., Investigator Operations Manual § 5.2.4 (2011).

After the 2009 inspection, Chung's attempted to preempt the issuance of a Form 483 containing any observation of its failure to include water activity as a secondary barrier for C. botulinum in its HACCP plan. (Doc. 30, Exh. A11 at 2.) Chung's warned:

> If there is a[n] FDA [Form] 483 observation on the water level activity issue Chung's will respond by contesting the findings of your Denver laboratory, contest what the actual definition of [a water activity level] above 0.97 means, and return to the dispute we have over the agency's attempt to use Guidance as though it were binding law. The resolution of those issues will require considerable resources of all concerned.

(*Id*.)

Chung's expert, Bluhm, questions whether 0.97 is an appropriate level for water activity, based on research relating to C. botulinum type E:

> I went back to FDA Guidance to confirm that the level of Water Activity suggested as a goal is 0.970. My research, however, shows that [] number is much higher than what is realistically required to effectively and safely protect the public. . . . Hobbs (1976) stated that at 10°C and at the optimum pH for growth, ***C. botulinum type E*** was inhibited by [a water activity level] of 0.990. I understand my conclusion that [a water activity level] of 0.990 is acceptable and safe is different than the FDA Guidance [water activity level] of 0.970 . . . .

(Doc. 30, Exh. C at 6.) In fact, the research cited by Bluhm is referenced by the FDA in its Guidance.[6] Fed. Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance app. 7 (3d ed. 2001).

Bluhm provides no other evidence contradicting the FDA's Guidance level of 0.97.

[6] "[T]he inhibitory [water activity] is 0.940 to 0.950 for proteolytic strains of types A and B and 0.970 to 0.975 for type E. At 20°C types A and B were inhibited by [water activity] of 0.970, and at 10°C type E was inhibited by [water activity] of 0.990." G. Hobbs, *Clostridium Botulinum and its importance in fishery products*, Advances in Food Research (1976). *See also* Addreas H.W. Hauschild, Karen L. Dodds, Clostridium botulinum: ecology and control in foods 174 (1993), which provides water activity ranges for sources cited by Bluhm ("Reported minimum water activities for growth of C. botulinum in NaCl-containing foods or media are 0.94-0.96 for types A and B and about 0.97 for type E (Baird-Parker and Freame, 1967; Denny et al., 1969; Emodi and Lechowich, 1969; Marshall et al., 1971; Ohye and Christian, 1967).")

According to his curriculum vitae, Bluhm has not published any research in this area. (Doc. 30, Exh. C1.) By contrast, the Government's expert, Doyle, has written over 250 peer reviewed articles and fifty-three book chapters relating to foodborne pathogens, including widely cited research on controlling C. botulinum in MAP-packaged food products. (Doc. 16, Exh. 4.)

E. Listeria Monocytogenes

Chung's disagrees with the FDA about the presence and control of Listeria monocytogenes ("L. mono") at its plant.

L. mono is a bacterium that tends to proliferate in moist niches such as floor drains and surfaces with condensation; it causes the rare but deadly disease listeriosis. (Doc. 16, Exh. 3 at 6.)

In 2005, the FDA detected L. mono in five different environmental swab samples at Chung's plant. (Doc. 16, Exh. 1I.) The FDA investigator observed that Chung's did not properly monitor the temperature and heat penetration of fried egg rolls to control growth of L. mono. (Doc. 16, Exh. 1H.)

In January 2006, Chung's informed the FDA that it had purchased a new fryer with temperature and speed monitors and that it planned to hire an outside tester to check for cold spots to determine the temperature and speed settings necessary to achieve the required heat penetration. (Doc. 16, Exh. 2E at 4.) In the meantime, Chung's promised to perform in-house L. mono testing on four to eight egg rolls per production run. (*Id.*)

In June 2006, the outside tester determined that the egg rolls did not achieve adequate heat penetration within the fryer, although adequate heat penetration occurred outside the fryer, as the egg rolls were carried on a conveyor belt toward the freezer. (Doc. 16, Exh. 1D at 5.) On August 7, 2006, the FDA informed Chung's that the test report "appears adequate," on the

condition that Chung's "add a dwell time requirement in the chill tunnel" to ensure proper cooking. (Doc. 16, Exh. 3D at 7.) Chung's responded that "a dwell time requirement will be added for the chill temperatures" and that it would designate "an appropriate point in the chill tunnel to monitor [the] product coming from the fryer to confirm that the temperature of the egg rolls" meets guidelines. (Doc. 16, Exh. 3D at 7.)

During the next inspection, in May 2007, the FDA investigator observed, "The [heat penetration] study states that the minimum [reduction in egg roll temperature, according to FDA guidelines] is achieved 10 minutes after the egg roll exits the fryer. There is [sic] no data listing the temperature of the product at ten minutes outside of the fryer. . . . The temperature of the chill room is not being monitored." (Doc. 16, Exh. 1D at 6.) The investigator also observed that the temperature of the chill room had "dropped as much as 40 degrees [Fahrenheit] since the study was conducted." (*Id.*) On October 30, 2007, the FDA issued a warning letter designating the temperature deviation a "significant violation." (Doc. 16, Exh. 2A.) In December 2007, Chung's announced that it would change its monitoring process. (Doc. 30, Exh. A4 at 6.) According to Chung's minutes of a meeting in March 2008, an FDA officer questioned the adequacy of the new monitoring process but ultimately agreed that it was adequate. (Doc. 30, Exh. A8 at 3.) The FDA officer pointed out that the heat penetration test itself was "sufficient to validate the fryers." (*Id.*)

At the next inspection, in 2009, the FDA investigator reported, "Mr. Birdsell stated that they threw out the study and they are not using it." (Doc. 16, Exh. 1F at 33.) The investigator determined that the new monitoring process could nonetheless be validated by the study and chose not to include the issue again as an observation on the Form 483, "even though [Chung's] has decided to ignore the findings and not reference the document to validate [its] cooking

process." (*Id.*)

Also during the 2009 inspection, the FDA investigator again took environmental samples and, as in 2005, found L. mono in multiple locations. (Doc. 16, Exh. 1E.) The samples were sent to the FDA's Denver District Laboratory for a DNA test, and digital images of the bacteria's DNA fingerprint were then sent to CFSAN in Maryland. (Doc. 16, Exh. 5 at 4.) An analyst at CFSAN compared them to the DNA fingerprint patterns from the 2005 samples and identified "a common strain of L. mono present in the Chung's plant that persisted from 2005 to 2009." (*Id.*) Both the 2005 and 2009 samples also tested positive for non-hazardous species of Listeria, including *Listeria innocua* and *Listeria welshimeri*, as did concurrent samples taken by Chung's. (Doc. 30, Exh. B at 6.)

Chung's expert, Bluhm, challenges the significance of these other Listeria species. (Doc. 30, Exh. C at 10.) "***L. innocua*** is widespread in the environment and in food is considered to be a nonpathogenic bacterium. More to the point, one positive ***L. innocua*** result is not alarming and is certainly no reason to enter a permanent injunction. The same can be said for ***L. welshimeri***." (*Id.*)

Consumer safety officer Losikoff of CFSAN testifies:

> Positive results for the presence of non-pathogenic forms of Listeria species ("L. spp."), such as L. innocua, in a production environment alerts a processor to the potential contamination of ready-to-eat product during processing because, generally, L. spp. is more easily detected than L. mono. Accordingly, the seventeen environmental swabs that tested positive for L. innocua are significant, and suggest that conditions also are suitable for survival and/or growth of L. mono.

(Doc. 16, Exh. 3 at 22.) The Government's expert, Doyle, agrees:

> The positive L. mono findings along with seventeen positive samples of L. innocua (another strain of Listeria that thrives under the same conditions as L. mono and is considered an indicator of potential L. mono contamination) suggest that these listeriae are widespread in Defendants'

> processing environment and must be controlled to ensure production of a safe food product.

(Doc. 16, Exh. 4 at 20.)

Chung's responds that the positive L. mono test results may have been caused by flawed collection practices. (Doc. 30 at 15.) Kujawa and Birdsell list many examples of possible cross-contamination during the sample collection process. (Doc. 30, Exh. A at 16, Exh. B at 11.) For instance, Birdsell accuses the FDA investigator of "touching his glasses and his nose" while holding a sample that tested negative for salmonella. (Doc. 16, Exh. B at 11.) Defendants cite only one example of possible cross-contamination involving a sample that tested positive for L. mono. In this instance, the FDA investigator, prior to taking the sample, put on gloves from a bag that had come into contact with another bag he had picked off the floor. (*Id.*) However, Defendants do not allege that the gloves touched either bag or the surface of the sample.

Chung's also questions the integrity of the samples during transport and processing by the FDA:

> The Government did not provide an evidentiary foundation for the alleged positive L. mono results from 2005 and 2009. The Government's summary judgment evidence is silent regarding the chain of custody of the samples, the tests performed on the samples, the qualifications of the technicians that tested the samples, and the validation of the laboratories in which the samples were tested.

(Doc. 30 at 14.) These items, however, are documented in the FDA laboratory's reports as well as the FDA investigator's report. (Doc. 16, Exhs. 1E, 5B, and 1F at 53.) Chung's expert witness does not mention Kujawa's and Birdsell's criticisms of the investigator's sampling protocol, aside from remarking, "I do not find anything stated by [the investigator] on how in 2005 or 2009 the collected samples were handled, chain of custody verified, and when the samples were tested." (Doc. 30, Exh. C at 11.)

There is disagreement between Defendants and the FDA about whether the L.mono test results were disclosed during the 2009 inspection. Chung's contends that the FDA's test results are suspect due to belated disclosure. (Doc. 30 at 14.) "There is no reason why the FDA would not provide timely notice of this claim—unless there were serious problems with the FDA's samples or test results." (*Id.*) The FDA investigator reported:

> I explained during the close-out of the inspection that the environmental samples that I collected on June 18, 2009 were both positive for Listeria monocytogenes and Listeria innocua. . . . I explained to both Mr. Birdsell and Mr. Kujawa that they should reevaluate their sanitation program due to the amount of positive samples that were collected during the inspection.

(Doc. 16, Exh. 1F at 38.)

Kujawa and Birdsell deny this version of events. Birdsell states that the investigator "never told me—or said in my presence—that the FDA laboratory testing in 2009 revealed the presence of **L. mono** in the Chung's facility. My memory is consistent with the contemporaneous notes taken by Chung's during the inspection, which do not reflect this alleged conversation." (Doc. 30, Exh. B at 12.) Kujawa testifies:

> At no time did [the FDA investigator] in my presence say that FDA had discovered the presence of L. mono in the Chung's facility in 2009. I know it did not happen (1) because of my memory of the event, (2) because if it had happened I would have instructed Gregory Birdsell, Chung's Director of Quality Assurance, to immediately implement our L. mono protocol and there would be a record of that event, (3) because Mr. Birdsell was present at the closing meeting and he recalls no such discussion, and (4) and perhaps most importantly, that discussion does not appear in the contemporaneous notes take by [Chung's employees] Shannon Trahan and Monica Patterson of what occurred and was said during the inspection by FDA and Chung's. . . . I have read the notes and they contain absolutely no mention of [the investigator] speaking of L. mono being present at the close out meeting when he issued the FDA 483.

(Doc. 30, Exh. A at 14.) However, Chung's minutes of the closing meeting, on which Kujawa and Birdsell rely, suggest that L. mono results were, in fact, disclosed:

> 12:58 FDA asked about Chung's test results for the environmental samples. Mr. Birdsell said they came back 100 percent clear.
> FDA claims they found L.innocua in some areas.
> 1:07 [The investigator] says the sanitation program is not working because two drains in the plant did not come back with good test results. Mr. Kujawa said we had Listeria species, but not Listeria monocytogenes.

(Doc. 30, Exh. D2.) "Two drains" refers to the location of the two samples where L. mono was detected, in contrast to "some areas" where L. innocua was found. (Doc. 16, Exh. 1E at 3.) Read in context, Chung's minutes strongly suggest it was aware of the positive L. mono test.

F. Staphylococcus Aureus

Chung's and the FDA disagree about the control of Staphylococcus aureus ("S. aureus") in Chung's facility. In 2005 and again in 2007, the FDA investigator observed that S. aureus was not included as a CCP in Chung's HACCP plan. (Doc. 16, Exhs. 1H at 3 and 1D at 5.) During the 2006 inspection, the FDA investigator observed employees repeatedly "placing hand-rolled egg rolls into a large unrefrigerated tank of batter in an assembly line. . . . Defendants did not routinely wash or sanitize this batter tank, and the temperature of the batter in the tank reached as high as 74 degrees Fahrenheit." (Doc. 16, Exh. 3 at 22.) S. aureus growth may occur at temperatures above 70 degrees. (*Id.*) The investigator also observed that Chung's employees failed to monitor the temperature. (*Id.*)

In its response to the 2006 Form 483, Chung's asserted that, since the inspection, employees had been retrained and backup monitors assigned. (Doc. 30, Exh. A19 at 5.) A batch of 7200 egg rolls from the day the FDA investigator observed the noncompliance was subsequently "held" by Chung's, tested for S. aureus, and then released for sale. (*Id.*)

Losikoff testified:

> In 2007, after Chung's had been cited twice for issues regarding the S. aureus hazard in its batter, rather than institute proper sanitation procedures, the firm disregarded batter temperature as a critical control

> point and removed batter temperature from its HACCP plan. . . . In 2009, [the] FDA observed that the firm was no longer using batter or dip buckets, however, because it has not instituted proper procedures or controls, there is nothing to prevent a restart of the same or similar insanitary practices.

(Doc. 16, Exh. 3 at 23.) Bluhm states, "I inspected the Chung's facility for several days in April 2010 and based upon my inspection and review it is my opinion that Chung's sanitation practices are adequate and that ***S. aureus*** is not a real risk or problem." (Doc. 30, Exh. C at 12).

G. Metal Detection

From 2005 to 2009, the FDA investigator observed that Chung's did not include metal detection as a CCP in its HACCP plan. (Doc. 16, Exhs. 1B, 1H, 1D.) Chung's HACCP plan stated:

> Process Step: Metal Detection
> Potential Hazard Introduced, Controlled Enhanced or Reduced at This Step: None identified at this time.
> Is The Potential Food Safety Hazard Reasonably Likely To Occur?: No
> Justification For Decision: None
> What Control Measures Can Be Applied To Prevent The Significant Hazard(s)?: None

(Doc. 16, Exh. 1B at 3.)

During the 2007 inspection, the FDA investigator observed a broken blade on a carrot slicer. (Doc. 16, Exh. 1D at 5.) Defendants responded that "it is very unlikely that metal would enter the product." (*Id.*) Chung's used a metal detector in its assembly line, as part of an in-house program for which no documentation is required. (Doc. 16, Exh. 1B.) Finally, in 2009, Chung's announced that it would list metal detection as a CCP. (Doc. 30, Exh. A17 at 5.)

H. USDA Inspection

In January 2010, the USDA completed a four-year comprehensive assessment of the production of chicken and pork egg rolls in Chung's facility and concluded that Chung's "is

capable and is producing a safe product." (Doc. 16, Exh. A12 at ¶ 4.) The USDA investigator reported that Chung's "maintains very high standards with regard to sanitation practices." (Doc. 16, Exh. A12 at ¶ DJ7.)

On January 13, 2010, the USDA collected environmental swabs that tested negative for L. mono. (Doc. 30, Exh. A12 at 5.) The date the USDA planned to take samples was announced in advance. (*Id.* at 8.)

In contrast to the FDA's assessment, the USDA investigator found that "all hazards reasonably likely to occur [were] identified" in Chung's hazard analysis. (Doc. 30, Exh. A12 at ¶ 1.) Procedures not included in its HACCP plan, such as Chung's "in-house program" to control C. botulinum by monitoring water activity, "are supporting and maintaining conditions for justification of hazards made in the hazard analysis." (*Id.* at ¶ H4g.) However, the USDA assessment mentions sixteen incidents of noncompliance from July 2010 to January 2011, involving "HACCP monitoring and execution" as well as sanitation problems. (*Id.* at 5.) The incidents of noncompliance involving sanitation included "food particles observed on food contact surfaces during pre-operational inspection and condensation issues observed during operational sanitation inspection." (*Id.*) The incidents "did not impact the establishment's ability to produce unadulterated product." (*Id.*) The investigator noted that "Mr. Birdsell and Mr. Kujawa were thanked for their cooperation and patience throughout the process of the [USDA inspection]." (*Id.* at 9.)

I. Chung's Independent Efforts to Comply

In April 2010, Chung's hired Bluhm to conduct an inspection. He testified:

> Based upon my professional experience as the Director of Field Programs at FDA, my knowledge of sanitation matters in food processing, my personal eyes-on inspection of the Chung's facility, my conversations with Chung's personnel, my review of the documents provided to me and under

> all the circumstances of this matter as more fully described below, I have come to the conclusion that the entry of a permanent injunction sought by the government in this case is not warranted with respect to MAP or general sanitation issues. I also conclude that Chung's has not ignored or failed to cooperate with the FDA such as to warrant the requested injunction.

(Doc. 30, Exh. C at 3.) Bluhm noted that "this is not to say that everything Chung's has done or is doing is perfect. . . . During my inspection of the facilities I did make several observations of conditions that, if changed, would reduce a potential sanitation problem." (Doc. 30, Exh. C at 4.) However, Bluhm asserted that

> it is extremely difficult to accept the statements . . . that Chung's does not pay attention to items on the 483s and that they, Chung's, will revert back to procedures predating the 2007 [inspection report] and attendant 483s. . . . There have been numerous changes to the facility, protocols and procedures over the years as well as positive changes in the personnel of the company. The plant and procedures/protocols followed and existing today in no way resembles that which was in place last year and certainly that which was existent from 2005–07 [sic].

(*Id.* at 10.)

The Government disputes Chung's "claim[s] to have taken steps to correct deficiencies" and argues that Defendants "cannot or simply will not implement a consistent and permanent system of competent practices on their own." (Doc. 34 at 17.)

After the FDA first documented the C. botulinum issue in 2005, Chung's explored various alternative methods for reducing the risk without listing C. botulinum as a CCP. (Doc. 16, Exh. 2E at 4.) No alternative methods were implemented. In January 2006, Chung's reported that it

> experimented with a number of different ingredient formulation changes attempting to create an acceptable (i.e. marketable) secondary barrier, but that to date none of the changes resulted in a product that would make it from an esthetical point of view in the market. One common formula change to create a secondary barrier was the addition of acid to the recipe. [Chung's vice president for research and development] Mr. Novak stated

> the result was the product with acid added tasted terrible. Chung's would lose customers because of the bad taste. [Chung's director of quality assurance] Ms. Ybarra said adding acid makes the product taste 'pickled.'

(*Id.*) In April 2006, Chung's reported,

> Since our January 2006 meeting Chung's has been fortunate to locate an expert in food safety who by happenstance is a faculty member at the University of Houston. . . . Chung's is considering a project with the professor to demonstrate the second barrier properties of nisin in MAP refrigerated egg rolls as well as its impact on the taste and aroma of egg rolls.

(Doc. 30, Exh. A18.)

By May 2006, Chung's had shifted its approach from researching ways to comply with FDA observations to validating its current formulation of egg rolls through testing. (Doc. 16, Exh. A19 at 2.) In response to the FDA's assertion that Chung's C. botulinum challenge study was flawed because it did not follow NACMCF protocol, Chung's argued that "in the experience of the [testing lab], when it develops challenges studies that follow the NACMCF guidelines[,] the projects are too expensive to be practicable." (Doc. 30, Exh. A4 at 4.)

Chung's expanded its testing program by undertaking an NFPA heat penetration study to verify critical temperatures for control of L. mono, which it alleged was "something few if any other food manufacturers have done." (Doc. 16, Exh. 3D at 8.) Prior to the release of the study, Chung's conducted in-house L. mono testing. (Doc. 16, Exh. 2E at 8.) "Chung's was proud of its new ability to do on-site microbiological testing, and that it raises the awareness of microbial safety throughout the business." (*Id.*)

In 2009, Chung's presented an "outside independent third-party shelf life study to determine if oxygen in MAP Shrimp egg rolls can be determined to be a secondary barrier to C. bot[ulinum]." (Doc. 16, Exh. A17 at 5.) FDA guidelines do not list oxygen content as a secondary barrier for C. botulinum. Fed. Drug Admin., Fish and Fisheries Products Hazards and

Controls Guidance (3d ed. 2001). The Government's expert, Doyle, testifies,

> Adding oxygen to MAP packaging does not diminish the C. botulinum risk. As demonstrated in multiple studies, addition of oxygen to MAP does not alter the anaerobic conditions of the food product. . . . MAP packing itself is not such a barrier; rather, it is a risk because it is what promotes C. botulinum toxin formation by creating a long-term reduced oxygen or anaerobic environment for a food product.

(Doc. 16, Exh. 4 at 5.) Bluhm does not mention the proposed use of MAP as a secondary barrier for C. botulinum, and Chung's provides no other expert testimony or scientific basis for it, aside from a lab report indicating oxygen levels in a sample of egg roll packages. (Doc. 30, Exh. A17, Sub-Exh. 2.)

During its meeting with the FDA in January 2006, Chung's objected to what it saw as selective enforcement by the FDA. Chung's asserted that, were it to comply with the FDA's proposed changes in its packaging to control C. botulinum, "Wal-Mart will simply stop purchasing Chung's egg rolls . . . and purchase more egg rolls from Chung's major competitor, Vans. . . . Losing the Wal-Mart business would be a devastating event to Chung's." (Doc. 16, Exh. 2E at 5.) According to Chung's minutes, FDA District Director Rodriguez "indicated that in the protection of public health 'somebody has to be first.'" (*Id.* at 4.)

Chung's proposed that the FDA "promulgate after notice and comment a legally binding regulation mandating a secondary barrier in MAP products" and "offered to work with FDA on such a proposal." (*Id.* at 5.) Rodriguez said he would "pass on the suggestion to [CFSAN]."

In a follow-up letter in May 2006, Chung's wrote, "Over the past several months Chung's has provided the Dallas office of FDA with a number of labels of MAP refrigerated food with use-by dates up to two or three times longer than the 28 days Chung's has used. There is no public indication that FDA has taken any steps with regard to any of the competitors of Chung's to achieve the level playing field to which Chung's volunteered." (Doc. 30, Exh. A19 at 2.)

On October 30, 2007, the FDA issued warning letters to Van's Foods and Chung's, citing violations for failure to control C. botulinum in MAP-packaged egg rolls. Fed. Drug Admin., Warning Letters No. 2008-DAL-WL-01 and -02 (October 30, 2007).[7] Chung's argues that its ongoing communication with the FDA in regard to Van's, among other issues, "proves that Chung's treated all of the FDA's concerns seriously" and "has not ignored FDA observations or warnings." (Doc. 5 at 6.)

J. Procedural History

On February 3, 2010, the Government issued a demand letter threatening suit unless Chung's agreed to a consent decree. On March 8, 2010, the Government filed the instant suit, bringing claims against Chung's, Kujawa, and Birdsell for failure to comply with the HACCP and sanitation provisions of 21 C.F.R. § 123 and for thereby rendering food products adulterated under 21 U.S.C. § 331(a) and (k). (Doc. 1.) The Government now moves for summary judgment and asks the Court to enter a permanent injunction enjoining Defendants from processing food until notified by the FDA that they are in compliance with the FDCA, all applicable regulations, and certain additional requirements. (Doc. 16, Proposed Decree ¶ 6I.)

The Government's proposed injunction includes provisions requiring that Chung's (1) retain an independent HACCP expert to conduct a hazard analysis and develop HACCP plans, SSOPs, and training programs acceptable to the FDA; (2) destroy all MAP-packaged fish or fishery products, or submit to the FDA within forty-five days an acceptable plan to bring such products into compliance; (3) perform product recalls or cease production as and when the FDA deems necessary; (4) permit and pay the costs of FDA inspections to enforce the injunction; and (5) pay damages of $3,000 for each day Defendants fail to comply with the injunction and $1,000 per day for each violation of the FDCA, applicable regulations, or the injunction. (*Id.* at

[7] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/default.htm.

6A, 6G, 9, 11, 18).

II. Standards of Review

A. Summary Judgment

A party moving for summary judgment must inform the court of the basis for the motion and identify those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, that show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The substantive law governing the suit identifies the essential elements of the claims at issue and therefore indicates which facts are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The initial burden falls on the movant to identify areas essential to the nonmovant's claim in which there is an "absence of a genuine issue of material fact." *Lincoln Gen. Ins. Co. v. Reyna*, 401 F.3d 347, 349 (5th Cir. 2005). If the moving party fails to meet its initial burden, the motion must be denied, regardless of the adequacy of any response. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (*en banc*). Moreover, if the party moving for summary judgment bears the burden of proof on an issue, either as a plaintiff or as a defendant asserting an affirmative defense, then that party must establish that no dispute of material fact exists regarding all of the essential elements of the claim or defense to warrant judgment in his favor. *Fontenot v. Upjohn*, 780 F.2d 1190, 1194 (5th Cir. 1986) (the movant with the burden of proof "must establish beyond peradventure *all* of the essential elements of the claim or defense to warrant judgment in his favor") (emphasis in original).

Once the movant meets its burden, however, the nonmovant must direct the court's attention to evidence in the record sufficient to establish that there is a genuine issue of material

fact for trial. *Celotex*, 477 U.S. at 323–24. The nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Indust. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (citing *U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962)). Instead, the nonmoving party must produce evidence upon which a jury could reasonably base a verdict in its favor. *Anderson*, 477 U.S. at 248; *see also DIRECTV Inc. v. Robson*, 420 F.3d 532, 536 (5th Cir. 2005). To do so, the nonmovant must "go beyond the pleadings and by [its] own affidavits or by depositions, answers to interrogatories and admissions on file, designate specific facts that show there is a genuine issue for trial." W*ebb v. Cardiothoracic Surgery Assoc. of North Texas, P.A.*, 139 F.3d 532, 536 (5th Cir.1998). Unsubstantiated and subjective beliefs and conclusory allegations and opinions of fact are not competent summary judgment evidence. *Morris v. Covan World Wide Moving, Inc.*, 144 F.3d 377, 380 (5th Cir. 1998); *Grimes v. Texas Dept. of Mental Health and Mental Retardation*, 102 F.3d 137, 139–40 (5th Cir. 1996); *Forsyth v. Barr*, 19 F.3d 1527, 1533 (5th Cir. 1994), *cert. denied*, 513 U.S. 871 (1994); *Topalian v. Ehrman*, 954 F.2d 1125, 1131 (5th Cir. 1992), *cert. denied*, 506 U.S. 825 (1992). Nor are pleadings summary judgment evidence. *Wallace v. Tex. Tech Univ.*, 80 F.3d 1042, 1046 (5th Cir. 1996) (citing *Little*, 37 F.3d at 1075). The nonmovant cannot discharge his burden by offering vague allegations and legal conclusions. *Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992); *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 889 (1990). Nor is the court required by Rule 56 to sift through the record in search of evidence to support a party's opposition to summary judgment. *Ragas v. Tennessee Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998) (citing *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915–16 & n.7 (5th Cir. 1992)).

Nevertheless, all reasonable inferences must be drawn in favor of the nonmoving party.

Matsushita, 475 U.S. at 587–88; *see also Reaves Brokerage Co. v. Sunbelt Fruit & Vegetable Co.*, 336 F.3d 410, 412 (5th Cir. 2003). Furthermore, the party opposing a motion for summary judgment does not need to present additional evidence, but may identify genuine issues of fact extant in the summary judgment evidence produced by the moving party. *Isquith v. Middle South Utilities, Inc.*, 847 F.2d 186, 198–200 (5th Cir. 1988). The nonmoving party may also identify evidentiary documents already in the record that establish specific facts showing the existence of a genuine issue. *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 178 (5th Cir. 1990).

B. Statutory Injunction

The FDCA expressly authorizes district courts to grant injunctive relief to enforce its provisions. 21 U.S.C. § 332(a).

The standard for a statutory injunction is different from the injunction standard for private litigants. *United States v. City and County of San Francisco*, 310 U.S. 16, 30–31 (1940); *United States v. FDIC*, 881 F.2d 207, 210 (5th Cir. 1989). The Government need not prove irreparable harm, because harm is presumed when a statute is violated. *E.E.O.C. v. Cosmair, Inc.*, 821 F.2d 1085, 1090 (5th Cir. 1987); *United States v. Dotterweich*, 320 U.S. 277, 285 (1943) ("Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless"). Food processors must meet an elevated standard of care. *United States v. Park*, 421 U.S. 658, 671 (1975) ("The public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors").

To support a permanent injunction under the FDCA, the Government must show that the

defendant has violated the statute and that there is "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Quadro Corp.*, 928 F. Supp. 688, 697 (E.D. Tex. 1996). When evaluating the risk of recurrent violations, courts consider "the bona fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations." *United States v. Bob Lawrence Realty, Inc.*, 474 F.2d 115, 126 (5th Cir. 1973), *quoting W.T. Grant Co.*, 345 U.S. at 633. The likelihood of future violations may be inferred from past unlawful conduct. *Commodity Futures Trading Comm'n v. British American Commodity Options Corp.*, 560 F.2d 135, 144 (2d Cir. 1977); *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987).

III. Discussion

The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated." 21 U.S.C. § 331(a). Food is adulterated within the meaning of the FDCA "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4). "Actual contamination is not required; it is sufficient that there exists a reasonable possibility of contamination." *United States v. Union Cheese Co.*, 902 F. Supp. 778, 786 (N.D. Ohio 1995), *citing United States v. H.B. Gregory Co.*, 502 F.2d 700, 704 (7th Cir. 1974); *see also United States v. Int'l Exterminator Corp.*, 294 F.2d 270, 271 (5th Cir. 1961). Federal regulations for fish and fishery processors provide that "[f]ailure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, [or] otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated

under section 402(a)(4) [21 U.S.C. § 342(a)(4)] of the act." 21 C.F.R. § 123.6(g).

Chung's shrimp egg rolls are "fishery products" under 21 C.F.R. § 123.3(e). Chung's operations constitute food "processing." 21 C.F.R. §§ 123.3(k)(1), 123.6. The Court may presume a connection with interstate commerce. 21 U.S.C. § 379a ("In any action to enforce the requirements of [the FDCA] respecting a food . . . the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist"); *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 42 (E.D.N.Y. 2001) *aff'd sub nom. United States v. Dozortsev, et al.*, 110 Fed. Appx. 197 (2d Cir. 2004). The Government also provided undisputed evidence that Chung's distributes its products in interstate commerce. (Doc. 1 at 3; Doc. 4 at 5.)

A. Sanitation

Between 2005 and 2009, the FDA documented many instances of unsanitary conditions at Chung's facility. During inspections in 2005, 2007, and 2009, FDA investigators observed unsanitary conduct by Chung's employees, such as inadequate handwashing. (Doc. 16, Exh. 1D, 1F, 1H.) In 2007, the FDA observed condensation dripping into egg roll filling. (*Id.*, Exh. 1D.) In 2009, the FDA observed an "oily brown substance" running down the length of the cooler where ingredients were stored. (*Id.*, Exh. 1B.) These observations are not disputed. In toto, these observations demonstrate that Chung's food was prepared under filthy conditions and that there is a reasonable possibility that Chung's food was "contaminated with filth" under 21 U.S.C. § 342(a)(4). "Congress intended that the word 'filthy', as used in the Act, should be construed to have its usual and ordinary meaning, and should not be confined to any scientific or medical definition." *Blue Ribbon*, 179 F. Supp. 2d at 50, *quoting United States v. Swift & Co.*, 53 F. Supp. 1018 (M.D. Ga. 1943). The Court finds that Defendants violated the FDCA by introducing into interstate commerce food that was prepared under insanitary and filthy

conditions. 21 U.S.C. § 331(a).

The Government has demonstrated the presence of a recurrent strain of L. mono in Chung's facility. (Doc. 16, Exh. 5.) This finding demonstrates a reasonable possibility that food produced in Chung's facility is unsafe and injurious to health. (Doc. 16, Exh. 4 at ¶ 50; Doc. 30, Exh. C at ¶ 33.) Chung's lengthy objections to the FDA's sample collection procedures do not overcome the Government's "presumption of regularity." *U.S. Postal Service v. Gregory*, 534 U.S. 1, 10 (2001) (holding that "a presumption of regularity attaches to the actions of Government agencies"); *Nash v. Estelle*, 597 F.2d 513, 518 (5th Cir. 1979); *Pasadena Research Laboratories v. United States*, 169 F.2d 375 (9th Cir. 1948) (applying the presumption of regularity to testing by FDA scientists). The presumption of regularity by itself does not satisfy the Government's burden at summary judgment; application of the presumption to summary judgment evidence, however, is not precluded. *See TK-7 Corp. v. FTC*, 738 F. Supp. 446, 449 (W.D. Okla. 1990) (applying the presumption to summary judgment evidence). The FDA's L. mono tests were reviewed by experts at the FDA and by both parties' expert witnesses. (Doc. 30 Exhs. 1B, 2, 3, 4, 5B; Doc. 16 Exh. C at 2.) Defendants fail to raise a genuine issue about the integrity of the tests.

In 2009, the FDA investigator observed that Defendants failed to maintain and make available Sanitation Control Records covering the minimum eight items required for seafood processors under 21 C.F.R. § 123.11. (Doc. 16, Exh. 1B.) The investigator also observed that Defendants failed to maintain and make available safety documentation for imported food products, as required by 21 C.F.R. § 123.9. (*Id.*) The Court finds that Defendants have violated the FDCA by failing to maintain and to make available to FDA investigators mandatory food safety records. 21 C.F.R. §§ 123.9, 123.11.

B. HACCP Requirements

A compliant HACCP plan must "[l]ist the food safety hazards that are reasonably likely to occur." 21 C.F.R. § 123.6(g).

> A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

21 C.F.R. § 123.6. From 2005 onwards, Defendants continually refused to list metal detection as a CCP in Chung's HACCP plan. (Doc. 16, Exhs. 1B, 1H, 1D.) Defendants argued that metal contamination in Chung's egg rolls was "very unlikely." (Doc. 16, Exh. 1D at 5.) The FDA considers metal detection a standard CCP for seafood processors. "[I]t would be reasonably likely to expect that metal fragments could enter the process from the following sources as a result of worn, damaged or broken equipment parts: . . . Blades from mechanical chopping or blending equipment." Fed. Drug Admin., *Metal Inclusion*, Fish and Fisheries Products Hazards and Controls Guidance (3d ed. 2001).[8] In 2007, the FDA investigator observed a broken metal cutting blade in Chung's facility. (Doc. 16, Exh. 1D at 5.) The HACCP Guidelines provide that

> the probability of metal contamination may be significant in one facility but not in another. A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

Fed. Drug Admin., Hazard Analysis and Critical Control Point Principles and Application Guidelines (August 14, 1997).[9] Defendants failed to provide any justification for not including metal contamination. (Doc. 16, Exh. 1B at 3.) After the 2009 inspection, Chung's reversed its

[8] *Available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/ucm119896.htm.

[9] *Available at* http://www.fda.gov/food/foodsafety/HazardAnalysisCriticalControlPointsHACCP/ucm114868.htm.

decision and announced it would add metal detection as a CCP. (Doc. 30, Exh. A17 at 5.)

Chung's refused to list batter temperature as a CCP to control growth of S. aureus. In 2007, "after Chung's had been cited twice for issues regarding the S. aureus hazard in its batter, rather than institute proper sanitation procedures, the firm disregarded batter temperature as a critical control point and removed batter temperature from its HACCP plan." (Doc. 16, Exh. 3 at 23.)

From 2005 onwards, Defendants continually refused to list C. botulinum as a CCP in Chung's HACCP plan. Failure to list C. botulinum as a CCP does not constitute a per se violation of the FDCA. Defendants' expert witness, Bluhm, testified that C. botulinum is not a reasonably likely hazard in Chung's facility under certain conditions:

> Because Chung's agreed to use Water Activity testing under FDA Guidance [and because the water activity] has tested in a range of values from 0.936 to 0.976, my conclusion is under these conditions ***C. botulinum*** type E is not reasonably likely to occur as a hazard . . . .

(Doc. 30, Exh. C at ¶ 23.) However, Defendants assured the FDA that they would keep water activity below 0.970, not 0.976, and, when they failed to do so, failed to take any corrective action. (Doc. 16, Exhs. 2C at 3, 3 at 25.)

Bluhm questions whether the FDA Guidance level of 0.970 is correct. (Doc. 30, Exh. C at ¶ 23). He bases his criticism of the FDA Guidance level on a research study that, in fact, was used by the FDA in determining the Guidance level. Fed. Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance app. 7 (3d ed. 2001). The Government's expert, Doyle, questions the relevance of Bluhm's criticism. "Regardless of the secondary barrier chosen as a critical control point, [e.g., keeping water activity below 0.97,] the only way to test its adequacy is to conduct a proper challenge study that includes a positive control." (Doc. 16, Exh. 4 at 14.) Defendants carried out a challenge study in 2006 that "establish[es]" and

"confirms . . . that C. botulinum is not reasonably likely to occur." (Doc. 16, Exh. 3C; Doc. 30, Exh. A4 at 5.) However, Doyle testified that the "test is flawed for many reasons." (Doc. 16, Exh. 4 at 15.) Bluhm does not address the challenge study nor its flaws, basing his opinion only on the cited research paper. (Doc. 16, Exh. C.)

Bluhm argues that the FDA's Guidance for seafood processors is nonbinding opinion based on the agency's "current thinking" rather than scientific consensus, which the FDA improperly uses to justify its institutional bias against MAP-packaged seafood products. (Doc. 20, Exh. C at 4, 8.) However, Bluhm fails to provide any relevant scientific evidence outside of the Guidance itself. (*Id.*) Moreover, guidelines for MAP-packaged seafood stricter than FDA Guidance have been widely adopted among non-FDA regulators. The FDA Food Code, a model code for state and local regulation that has been adopted by forty-nine states, including Texas, requires that MAP-packaged food have a labeled storage temperature of 41°F, along with a secondary barrier for C. botulinum and several other requirements with which Chung's egg rolls do not comply. Fed Drug Admin., FDA 1997 Food Code § 3-502.12. MAP-packaged foods are required to have a shelf life of fourteen days and an HACCP plan listing C. botulinum that specifies "methods for maintaining food at 5°C (41°F) or below." (*Id.*) Water activity must be maintained below 0.91. (*Id.*)

Bluhm claims that C. botulinum is not "reasonably likely" to persist under temperature conditions maintained by the "majority" of purchasers of its products, an assertion undermined by the "known likelihood" of variability in refrigeration temperatures in supermarket display cases, deli meat counters, and home refrigerators. (Doc. 30, Exh. C at 7; Doc. 16, Exh. 4 at 8.) Bluhm testified that C. botulinum was not a reasonably likely hazard in Chung's egg rolls based on a study of C. botulinum under controlled temperature and water activity conditions. (Doc. 30,

Exh. C at 7.) Temperature control is of "utmost importance" in controlling C. botulinum growth, and temperature abuse is often implicated in C. botulinum outbreaks. (*Id.* at 8.) According to the FDA, a "constant temperature of 38 degrees Fahrenheit (or lower) is required to inhibit the growth and toxin formation of C. Botulinum in Chung's seafood egg rolls as currently processed." (Doc. 16, Exh. 3 at 10.) The FDA and the Government, however, cite research showing that 63% of supermarket retail cases are kept above 38°F. (*Id*. at 11.) Nine percent of deli meat counters are above 50°F. (*Id.*) Chung's labels classifies its refrigerated egg rolls as "fresh/deli meat," making it likely that they will be stored in deli meat counters kept above 50°F. (*Id.*)

Between 2005 and 2009, Chung's resisted the FDA's recommendation to label its egg rolls with a maximum storage temperature of approximately 38°F. (Doc. 30, Exh. A8, A19, 2E, 3D.) After the 2005 inspection, the FDA recommended Chung's label its egg rolls with a maximum storage temperature of 37.9°F. (Doc. 30, Exh. 2E at 6.) Chung's labeled its egg rolls with a maximum storage temperature of 45°F. (Doc. 30, Exhs. A8 at 3, A19 at 2.) Chung's argued that lowering the labeled temperature further would give an unfair advantage to its competitors. (Doc. 30, Exh. 3D at 7.)

> While it is possible for manufacturers to change the labeling on their MAP products to 40°F, the problem with 40°F (a part of the FDA Guidelines) is that [the] FDA has not pushed retailers to reduce their cold cabinets to 40°F from 45°F, a temperature level retailers have followed for many years. This means a manufacturer that changes its labeling to 40°F loses business to other manufacturers with a 45°F or less label, because that is what retailers expect to see. FDA has it within its power to force 40°F storage temperatures on retailer deli and open-top cold boxes. By following that course everyone in the marketplace is on the same field with the result that across the board storage temperatures would go to 40°F.

(*Id.*) In 2008, after receiving a warning letter from the FDA, Chung's lowered the labeled

temperature to 40°F. (Doc. 30, Exh. A9 at 1.) Finally, in 2009, Chung's agreed to lower the labeled temperature to 38°F. (Doc. 30, Exh. A17 at 2.)

The FDA has not sought to force seafood retailers to maintain 40°F storage temperatures. Fed. Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance 11 (4th ed. 2011).

> It is now noted that critical limits that specify a cumulative time and temperature of exposure to temperatures above 40°F (4.4°C) are not ordinarily suitable because of the difficulty in determining when specific products have entered and left the cooler and the time and temperature exposures to which they were subjected.

(*Id.* at 11.)

Chung's did not raise the fairness issue again, nor does the record show any indication that Chung's revised labeling had any impact on customers' behavior. Given that retailers and consumers likely disregard or exceed the labeled temperature, along with Chung's reluctance to label its products within the recommended maximum storage temperatures, it would be unreasonable to rely on such labels to ensure the safety of Chung's food products.

Defendants' expert, Bluhm, testifies that holding Chung's responsible for storage temperatures not in accordance with product labeling would be too onerous. (Doc 30, Exh. C at 5.)

> Dr. Doyle and Mary Losikoff of FDA both criticize MAP seafood even where properly processed and labeled for shelf life on the grounds that the retailer may allow the product to be exposed to temperatures in excess of the label. Since there is no way for the processor to control what a retailer does, the conclusion they reach is MAP seafood should not be available to the public. My view is just the opposite. The responsibility of the manufacturer is to produce a safe product that is properly labeled for safe use. By analogy, under FDA view, a gun manufacturer should not produce and sell a gun that is properly manufactured and labeled because a gun retailer might violate the law and sell a gun to a convicted criminal.

(*Id.*) The burden of food safety, however, is squarely on food manufacturers. *United States v.*

Park, 421 U.S. 658, 672 (1975); *Smith v. California*, 361 U.S. 147, 152 (1960); *United States v. Dotterweich*, 320 U.S. 277, 285 (1943).

Defendants argue that "[t]he Government does not cite a single case, statute, or regulation saying that the use of [Modified Atmosphere Packaging in Chung's products], in and of itself, violates the Act. Instead, the Government is trying to enforce FDA Guidance, which 'does not operate to bind [the] FDA or the public.'" (Doc. 30 at 3, *quoting* Fed. Drug Admin. Fish and Fisheries Products Hazards and Controls Guidance (3d ed. 2001).) The FDA Guidance actually states, "Processors may choose to use other control measures, as long as they provide an equivalent level of assurance of safety for the product. However, processors that choose to use other control measures (e.g., critical limits) are responsible for scientifically establishing their adequacy." (Doc. 30, Exh. C at 4.)

The FDA acknowledges that its Guidelines are only "a guidance document that represents the agency's best thinking at the time, but that Chung's must show a rationale for why the product is safe against *Clostridium botulinum* for the shelf life claimed, under conditions of mild abuse." (Doc. 16, Exh. 2E at 3.) Defendants therefore had the option of following FDA Guidelines or implementing "other control measures, as long as they provide an equivalent level of assurance of safety for the product." (Doc. 30, Exh. C at 4.) Chung's attempted to meet this standard by carrying out the flawed challenge study and unsuccessfully attempting to implement an in-house program to verify that water activity remained below 0.97.

Chung's argues that listing C. botulinum as a CCP "would be inconsistent with HACCP principles" and "violate the rules that have made the HACCP process successful." (Doc. 30, Exh. A17 at 3.) Specifically, Chung's contends that water activity, the proposed critical limit[10]

[10] "Critical limit: a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard."

for C. botulinum, is a "stand alone process" that cannot "in and of [itself] eliminate or reduce the likely occurrence of the hazard," and thus C. botulinum fails to meet "that key criteria defining a CCP (i.e., one step where a control measure can be applied to eliminate, reduce or prevent a hazard from occurring)." (Doc. 30, Exh. A17 at 5.) Bluhm asserts that "listing water activity as a CCP would not be possible because under HACCP standards, testing would have to take place every time MAP shrimp/seafood were processed, not quarterly." (Doc. 30, Exh. C at 6.)

In fact, FDA Guidelines for monitoring water activity in seafood products suggest combining quarterly water activity analysis with continuous monitoring of proxy measurements such as cooking time and temperature logs. Fed. Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance ch. 14 (3d ed. 2001). The FDA's general HACCP guidelines do not specify the frequency of monitoring, stating only that "[w]hen it is not possible to monitor a CCP on a continuous basis, it is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the CCP is under control. Statistically designed data collection or sampling systems lend themselves to this purpose." Fed. Drug Admin., Hazard Analysis and Critical Control Point Principles and Application Guidelines (August 14, 1997); 21 C.F.R. § 123.6(c)(4).

The Court finds that the Defendants' attempt to use water activity as a secondary barrier for C. botulinum was inadequate to ensure their food product's safety. C. botulinum is a "reasonably likely" hazard that must be listed as a CCP on Chung's HACCP plan.

The Court further finds that Defendants failed to establish and implement sufficient measures to control contamination by C. botulinum, metal, and S. aureus, a violation of the FDCA's requirement that seafood processors have and implement a compliant HACCP plan,

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Fed. Drug Admin., Hazard Analysis and Critical Control Point Principles and Application Guidelines (August 14, 1997).

pursuant to 21 U.S.C. § 331(a).

C. Mootness

On December 21, 2007, Chung's told the FDA that it would cease producing refrigerated MAP-packaged egg rolls and that it would "exhaust all of its inventory" of such egg rolls by June 30, 2008. (Doc. 30, Exh. A5.) Chung's reversed its decision a month later. (Doc. 30, Exh. A6.) On February 6, 2008, Chung's attorney wrote, "I realize this is a change in thinking, we want to very much resume setting up a meeting" to discuss continued processing of MAP-packaged egg rolls. (*Id.*)

Chung's claims it has now ceased production of MAP-packaged egg rolls, and therefore the FDA's observations regarding C. botulinum risks and controls are moot. (Doc. 4 at 11.) "It has now been over one (1) year—from January 2010 to February 2011—since Chung's last produced MAP shrimp/seafood. Chung's has decommissioned and completely removed its MAP machines and all associated equipment from the production floor." (Kujawa Decl., Doc. 47 at 1.) Bluhm testified, "During my visit to Chung's in April 2010 I observed a MAP processing machine that had been removed from the production room to a space outside under cover where it awaits sale." (Doc. 16, Exh. C at 3.)

The Government responds that Defendants

> previously advised [the] FDA that they would stop using this type of packaging, but then changed their mind. . . . Defendants' current assurances that they have stopped using MAP are nothing more than an effort to avoid injunctive relief, and without an order from this Court there will be nothing to stop them from returning to their non-compliant ways as soon as this lawsuit is over.

(Doc. 34 at 16.)

Chung's cessation of production does not necessarily make the FDA's observations moot. *Donovan v. Cunningham*, 716 F.2d 1455, 1461 (5th Cir. 1983) ("It is well-settled that, in a suit

for injunctive relief, the voluntary cessation of allegedly illegal conduct does not moot the controversy arising from the challenged activity. . . . This is because the defendant is free to return to his old ways."); *see E.E.O.C. v. Rogers Bros.*, 470 F.2d 965, 966 (5th Cir. 1972) (holding that in determining defendants' likely future conduct, the court need look no further than defendants' past record with the FDA). The Government argues that "if Defendants' assertions of cessation in their answer are true, they should have no problems agreeing to the government's proposed decree, which simply seeks to ensure that Defendants have controlled for [C. botulinum] and developed and implemented a proper sanitation program . . . ." (Doc. 16 at 34.) The FDA's observations of food safety concerns involving MAP-packaged products remain relevant for assessing the danger of violations involving other products produced at Chung's facility. *W.T. Grant Co.*, 345 U.S. at 633. The Court finds that the FDA's observations regarding C. botulinum risks in MAP-packaged egg rolls produced at Chung's facility are not moot.

D. Chung's History of Violations and Noncooperation with the FDA

In considering a permanent injunction, the Court must determine if there is a cognizable danger of recurrent violation of the FDCA. *W.T. Grant Co.*, 345 U.S. at 633. Defendants have shown a history of recurrent violations and a pattern of not cooperating with the FDA. At the most recent inspection, in 2009, the FDA investigator documented fourteen instances where the Defendants refused to provide information and "personally impeded" the entry of investigators. (Doc. 16, Exh. 1F at 52.)

Defendants have also disregarded numerous Form 483 inspectional observations by FDA investigators. (Doc. 30, Exh. C3.) Form 483 observations are notifications of "factual observations of significant deviations from the [FDCA], [Public Health Service] Act, 21 CFR,

and other acts where FDA has enforcement authority," exceeding mere noncompliance with FDA guidance or policy. Fed. Drug Admin., Investigator Operations Manual § 5.2.3 (2011). The observations are discussed in person and signed by the "highest management official available" at a facility. Fed. Drug Admin., *supra* at § 5.1.1.4; 21 U.S.C. § 374(b).

During every inspection from 2005 to 2009, the FDA observed Defendants' failure to include metal detection as a CCP. (Doc. 16, Exhs. 1B, 1H, 1D.) Defendants provided no justification for this repeated failure. (Doc. 16, Exh. 1B at 3.) Similarly, after the FDA observed deviations in monitoring of temperatures in the chill tunnel and the batter tank, Chung's failed to implement agreed procedures for addressing these problems without providing any justification. (Doc. 16, Exh. 3 at 23, Exh. 1D at 6.)

Defendants provided misleading explanations for observed deviations. In response to the observation that Defendants failed to reassess their HACCP plan after changing the product formulation by switching from fresh to dehydrated onions, Defendants asserted that the observation was "simply not correct," since they had undertaken water activity testing on the egg rolls "before the change, during the change and following the formula change." (Doc. 30, Exh. A17 at 6.) Defendants do not explain how testing water activity at those times constitutes reassessment of the HACCP plan.

Seafood processors are required to have an HACCP-trained individual reassess their HACCP plan "whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in . . . raw materials or source of raw materials [and] product formulation." 21 C.F.R. § 123.8(a)(1). Chung's HACCP Updates Documentation Page does not reflect that the plan was reassessed upon changing the product's formulation. (Doc. 16, Exh. 1F at 54.)

Defendants contend that they never denied FDA investigators access to Sanitation Control Records, although they only provided full access to HACCP and SSOP documents. (Doc. 30, Exh. A at 23.) FDA regulations require that all Sanitation Control Records for frozen seafood be retained for two years and "be available for official review and copying at reasonable times." 21 C.F.R. § 123.9. When Chung's did provide a limited selection of records, it gave inconsistent explanations as to whether the checklists referred to Chung's GMP or SSOP policies. (Doc. 30, Exh. A17 at 10.) Both policies partially cover the eight items required by 21 C.F.R. § 123.11. Moreover, the eight required items, which apply specifically to seafood processors, overlap to some extent with the "Good Manufacturing Practices" required by Part 110 of the regulations that apply to all food processors. 21 C.F.R. § 110. *See The Statutory Basis for the FDA's Food Safety Assurance Programs: From GMP To 1995*, 50 Food & Drug Law Journal, 357 at 376 ("[T]he section 123.10 control procedures are identical in many respects to the previously prescribed GMPs in part 110 of the regulations.") However, only Part 123 requires sanitation recordkeeping. Birdsell should have been aware of this key requirement, as he was responsible for providing Chung's "annual extensive GMP training course to all employees." (Doc. 30, Exh. A17 at 10.)

Defendants also denied access to importation documents, in violation of the regulation mandating that "[a]ll records required by this part shall be retained at the processing facility or importer's place of business in the United States." 21 C.F.R. § 123.9. This regulation sets forth recordkeeping requirements for both domestic processors and importers of fishery products. (*Id.*) It requires that records of domestic or imported fishery products introduced in interstate commerce be made available to FDA investigators in the United States. (*Id.*) Importers of seafood must make available to FDA investigators "written verification procedures" ensuring

compliance with HACCP regulations in the foreign facility. 21 C.F.R. § 123.12(a). The required procedures must include (1) product specifications and (2) "affirmative steps" that "provide an equivalent level of assurance of compliance" as required for domestic facilities. *Id*. Affirmative steps might include, inter alia, HACCP and sanitation records from the foreign facility or "a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance" with HACCP regulations. *Id.*

Defendants failed to provide the necessary documentation and denied their obligation to do so. (Doc. 16, Exh. 1F at 54.) The FDA investigator reported, "Both Mr. Birdsell and Mr. Kujawa refused to provide this information during the inspection. Mr. Kujawa stated that it was not within the scope of my inspection even after I pointed out the specific import regulation during our discussion." (*Id.*)

Defendants again misled the FDA investigator in 2009, when they prevented the investigator from entering the onion frying room by claiming it was being used for USDA-regulated products. The FDA has broad authority to inspect the facility "at reasonable times and within reasonable limits and in a reasonable manner." 21 U.S.C. § 374; *see also* Fed. Drug Admin., Investigator Operations Manual § 3.1.3.1 ("Ingredients or manufacturing processes common to both USDA and FDA regulated products should be inspected by FDA."). In fact, Chung's uses the same onion ingredient and onion frying process for FDA- and USDA-regulated egg rolls. (Doc. 16, Exh. 1F at 13; Doc. 30, Exh. A10 at 1.) Chung's "do[es] not differentiate their procedures, recordkeeping or sanitation based on the type of product being produced." (Doc. 30, Exh. A12.) Whether or not Chung's designated a certain batch of onions for an FDA- or USDA-regulated product, the FDA had a reasonable basis for observing the process.

The FDA also had a compelling reason for wanting to observe fried onions being moved

to storage, as this procedure was the subject of observations on three previous Form 483s. (Doc. 16, Exhs. 1G at 2, 1H at 2, 1D at 2.) During each inspection, cooked onions and onion-frying oil were reported to have been stored improperly. (*Id.*) Chung's sought to take advantage of the overlapping jurisdiction of the FDA and the USDA to avoid inspection.

Defendants' response to the FDA's L. mono findings further demonstrates a lack of good faith in their dealings with the FDA. Defendants claim they are prepared to "immediately implement [their] L. mono protocol" upon any indication of L. mono. (Doc. 30 at 19.) However, they patently denied the possibly that the FDA may have found pathogenic L. mono in their facility in 2009. (Doc. 30, Exh. D2.) Their only possibly relevant objection to the findings was that one of the positive test samples may have been contaminated by touching a bag that touched the floor of the facility. (Doc. 16, Exh. B at 11.) However, the floor was also subject to environmental testing. *See* Fed. Drug Admin., Environmental Sampling for the Detection of Listeria monocytogenes, Investigator Operations Manual exh. 4-20 (2011). Even in Defendants' unlikely account, in which samples from the drain and floor may have been cross-contaminated, the tests indicated a reasonable likelihood that Chung's products were contaminated by L. mono. Defendants' objections to the L. mono tests, undertaken according to standard FDA testing protocol, were not only frivolous but demonstrated wanton disregard of a potential food safety hazard in its products.

The record shows that relations between Chung's and the FDA were highly strained. In 2006, the attempt to verify the safety of Chung's egg rolls through a challenge study was marred by miscommunication. After the meeting in January 2006, the parties agreed to a schedule for assessing C. botulinum risks, including the challenge study to be completed in June of that year, with an interim report in March, and a final proposal in June. (Doc. 16, Exh. 2E at 9.) In April

2006, the FDA conducted an inspection and listed the lack of a secondary barrier on the Form 483 as a "repeat violation," without mention of the ongoing study. (Doc. 16, Exh. 1G.) Chung's complained about the premature observation but failed to provide both the interim report in March and the final proposal in June. (Doc. 30, Exh. A19 at 2.) In 2009, Chung's minutes indicate that shortly before discussing test results, the FDA investigator "assured Mr. Birdsell that he was only trying to understand our process, not attempting to be hateful." (Doc. 30, Exh. D2.)

Chung's repeated use of an unsanitary water hose suggests miscommunication by both parties. When Bluhm saw that the water hose was a sanitation problem in April 2010, four years after the FDA first observed it, he "suggested the water hoses . . . be put on retractable rollers so they will not remain on the floor when not in use." (Doc. 30, Exh. C at 4.) Kujawa testified, "Chung's has adopted and implemented all of Dr. Bluhm's recommendations." (Doc. 50 at 2.) Chung's should have corrected the issue earlier, yet in spite of standard FDA Guidance the Form 483s observations do not indicate that retractable hoses were ever suggested. Fed. Drug Admin., Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods (2008).[11]

E. Statutory Injunction

The FDCA provides broad authority for district courts to restrain violations of the statute through injunction proceedings. 21 U.S.C. § 332(a). Chung's claims that the Government's proposed injunction is "plainly excessive" in light of more severe noncompliance described in other cases. In particular, Chung's objects to provisions requiring it to stop production of all

[11] *Available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm ("To prevent hose nozzles and employee hands from becoming contaminated, we recommend that you keep hose nozzles off the floor or other unclean surfaces unless they are not intended to make contact with RF-RTE food, food-contact surfaces, or packaging material. For example, you could install and use automatically retractable hoses (including spring tension or spring loaded retractable hoses) or fixed length hoses that do not touch the floor.").

food products and granting the FDA authority to order recalls and cessation of production. (Doc. 30 at 32.) The Government argues the provisions are "essential to ensure Defendants' compliance with the law. . . . Identical provisions are almost invariably included in FDA consent decrees and proposed orders and are routinely accepted and imposed by federal courts across the country . . . ."[12] (Doc. 34 at 18.)

The Government points out that power to stop production "would be invoked only if Defendants violate the law." (Doc. 34 at 19.) In *United States v. Blue Ribbon*, a district court addressed similar arguments:

> The injunction . . . will not require [Defendants] to stop processing fish but, rather, to stop processing fish that is or has become adulterated. . . . [D]efendants argue that the proposed injunction would "empower [the] FDA to micro-manage [Defendants'] facility" and that they should not have to pay for FDA inspections to ensure their compliance with the injunction or hire an outside consultant to monitor food safety. These objections to the proposed injunction do not merit an alteration of its terms. The terms of the proposed injunction, including the responsibility for costs and monitoring by outside consultants, have been routinely accepted and imposed by other courts faced with similar proof of FDCA violations.

Blue Ribbon, 179 F. Supp. 2d at 50 (internal citations omitted). The court noted that "the government is not seeking a harsher remedy, like criminal penalties, pursuant to 21 U.S.C. § 333, or seizure of defendants' products, pursuant to 21 U.S.C. § 334." *Id.* at 50 n.12.

Unlike Chung's, the defendants in *Blue Ribbon* did not dispute some of the FDA's observations about its HACCP plan and test results showing L. mono in its facility. In *Blue Ribbon*, the FDA found L. mono in the defendants' product samples as well as in environmental

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In 2010, the FDA obtained 10 injunctions against food processors. Fed. Drug Admin., FDA Enforcement Statistics Summary Fiscal Year 2010, *available at* *http*://www.fda.gov/downloads/ICECI/EnforcementActions/UCM247845.pdf. "Because injunctions are resource intensive for the FDA (e.g. the injunctions must be monitored), injunctions are rarely sought by the FDA and generally are only used when all other enforcement actions have been exhausted without success. Recurrent violations are generally the cause for seeking an injunction." Neal D. Fortin, Food Regulation: Law, Science, Policy, and Practice ¶ 12.5.3 (Wiley 2009).

samples, and sanitation conditions in the defendants' facility appeared to have been worse than in Chung's. *Id.* Both cases involved observations of condensation dripping into food products, mold or other filth, lax employee hygiene, and general disrepair. The defendants in *Blue Ribbon* claimed to have addressed all of the FDA's concerns by implementing "thirty corrective actions," rewriting their HACCP plan and sanitation policy, remodeling their factory, and instituting an employee sanitation supervisor. *Id.* at 36. Despite these changes, the court held that, based on their past conduct, "defendants cannot satisfy the burden to establish that 'there is no reasonable expectation that the wrong will be repeated.'" *Id.* at 50, *quoting W.T. Grant*, 345 U.S. 629 at 633.

The Government also points to *United States v. Union Cheese Co.*, 902 F. Supp. 778, 791 (N.D. Ohio 1995), in which the court granted a similar injunction. In that case, the FDA observed condensate dripping onto food products, "more than 30 floating dead flies" in a vat used for cheese production, and general disrepair, including a hole in the roof, a live bird, rusty implements, and absence of hot water for handwashing. *Id.* at 780. The defendants' expert witness disputed the FDA's conclusions, testifying that "based on his experience, neither filth nor insanitary conditions was present." *Id.* at 784. Denying there were insanitary conditions, the court wrote, was "frivolous, if not unconscionable." *Id.* at 787.

The defendants in *Union Cheese* also disputed the FDA's findings of L. mono, asserting that their own tests of numerous "parallel" samples did not detect L. mono and suggesting that the FDA's samples had been compromised during transportation and were "suspect." *Id.* at 784. The court dismissed these allegations, pointing out that "it is [the defendants'] position that L. mono is 'everywhere' and if one tests long enough and hard enough, it will be found." *Id.* at 783. Particularly relevant to the instant case was the court's determination that "[t]he fact that

listeria strains other than L. mono were identified as recently as May 1995 indicates that Union Cheese is not adequately sanitized to prevent the growth of bacteria within the listeria genus, including L. mono." *Id.*

Like the defendants in *Union Cheese*, Chung's asserts that FDA samples may have been compromised during collection and transportation. (Doc. 30 at 15.) Chung's points to "red flags regarding Pulsenet," the system the FDA uses to consolidate DNA fingerprints of food pathogens found in food processing facilities. (Doc. 30 at 20.) These alleged red flags include (1) a nine-month delay in processing and (2) a lack of "essential information" about how the FDA laboratory was validated. (*Id.*) Chung's provides no evidence or rationale for these assertions, aside from conclusory statements by its expert witness. (*Id.*)

Like the defendant in *Union Cheese*, Chung's seeks to diminish the importance of the FDA's results on the basis of the alleged prevalence of L. mono, while relying heavily on its own test results to suggest an absence of L. mono in its facility. "Because ***L. mono*** does occur so naturally in the ingredients used by Chung's . . . it may be just as likely that ***L. mono*** came in with the raw vegetables as it is that ***L. mono*** is persistent in Chung's." (Bluhm Decl., Doc. 30, Exh. B at 20.) Chung's litany of hypothetical flaws in the FDA's testing procedure do not raise genuine questions of fact.

While *Blue Ribbon* and *Union Cheese* appear to involve worse sanitary conditions than those alleged in Chung's facility, those cases arose from FDA inspections prior to the 1997 enactment of HACCP standards for seafood processors. By contrast, the Defendants here claim to have over ten years of experience with HACCP. (Doc. 30, Exhs. B at 3, A at 3.)

The Government cites two recent unpublished decisions granting similar injunctions on a motion for summary judgment. In *United States v. A. Chau Sprouting Co. et al.*, No. 10-cv-877

(E.D. La. June 21, 2010), the court found mold and mildew in a sprout farm, but no evidence of pathogens was presented. *Id.* In *United States v. Rel's Foods, Inc.*, No. 09-cv-4724 (N.D. Cal. Nov. 3, 2009), the court found L. mono, among other strains of Listeria, in prepared sandwiches as well as environmental samples in a small sandwich-making facility. As in Chung's facility, defendants were observed repeatedly using unsanitary water hoses, in spite of multiple warnings from the FDA that the hoses created a risk of L. mono contamination. *Id.* FDA Pulsenet analysis indicated that there was a persistent strain of L. mono. *Id.* The court entered an injunction requiring "all food products in contact with a site that tests positive for the general strain *L. spp.*," including Listeria found on surfaces not in contact with food, be held pending laboratory tests for L. mono in the finished product. *Id.* In addition, in the event of positive tests for any strain of Listeria, the defendants would have to carry out intensified daily Listeria testing throughout the facility, as outlined in mandatory Sanitation Standard Operating Procedures (SSOPs). *Id.*

Courts have also granted similar injunctions in cases involving drugs or medical devices. *United States v. Endotec, Inc.*, No. 06-cv-1281, 2009 U.S. Dist. LEXIS 93985, at *22–29 (M.D. Fla. Sept. 28, 2009); *United States v. Vita-Erb, Ltd.*, No. 05-cv-3494, 2006 U.S. Dist. LEXIS 82968, at *12–29 (W.D. Mo. Nov. 14, 2006); *United States v. Livdahl*, 356 F. Supp. 2d 1289, 1290–95 (S.D. Fla. 2005); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 582, 582–87 (D.N.J. 2004), *aff'd*, 427 F.3d 219 (3d. Cir. 2005); *United States v. RX Depot, Inc.*, 290 F. Supp. 2d 1238, 1250–52 (N.D. Ok. 2003); *United States v. Syntrax Innovations, Inc.*,149 F. Supp. 2d 880, 885–91 (E.D. Mo. 2001); *United States v. Universal Mgmt. Servs., Inc.*, 999 F. Supp. 974, 981–87 (N.D. Ohio 1997), aff'd,191 F.3d 750 (6th Cir. 1999); *United States v. Richlyn Labs., Inc.*, 822 F. Supp. 268, 274 (E.D. Pa.1993); *United States v. Vital Health Prods.*, 786 F. Supp.

761, 779–80 (E.D. Wis. 1992), *aff'd sub nom. United States v. LeBeau*, 985 F.2d 563 (7th Cir. 1993). In another case, the district court initially granted an injunction lacking provisions giving the FDA the authority to stop production and order recalls, but later amended the injunction to include the provisions due to impracticality of enforcement. *United States v. Mid-Florida Bakeries, LLC et. al.* No. 04-cv-1272 (M.D. Fla. June 9, 2005).

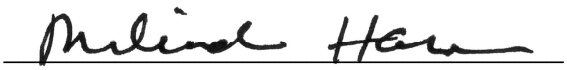
Defendants have repeatedly flouted FDA observations and failed repeatedly to provide adequate documentation regarding sanitation and required controls for C. botulinum, or an adequate hazard analysis justifying its exclusion as required by 21 C.F.R. § 123. The Government demonstrated a persistent strain of L. mono is present in Chung's factory from 2005 to 2009. Rather than cooperate with the FDA to resolve this problem, Chung's raised implausible objections to the FDA's testing procedures. Based on Chung's record of noncompliance, the Court finds a cognizable danger of future violations necessitating a permanent injunction.

IV. Conclusion

Evaluating all the evidence on the Government's motion for summary judgment in a light most favorable to nonmovants Chung's Products, LP, Charlie A. Kujawa, and Gregory S. Birdsell, the Court finds no genuine issue of material fact regarding whether Defendants are in violation of 21 U.S.C. § 331(a) and (k).

Accordingly, the Court hereby **ORDERS** that the Government's Motion For Summary Judgment (Doc. 16) is **GRANTED**.

SIGNED at Houston, Texas, this 3rd day of April, 2013.



MELINDA HARMON
UNITED STATES DISTRICT JUDGE